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# Adding web-based behavioural support to exercise referral schemes for inactive adults with chronic health conditions: the e-coachER RCT

Taylor, Adrian

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# Adding web-based behavioural support to exercise referral schemes for inactive adults with chronic health conditions: the e-coachER RCT

*Adrian H Taylor, Rod S Taylor, Wendy M Ingram, Nana Anokye, Sarah Dean, Kate Jolly, Nanette Mutrie, Jeffrey Lambert, Lucy Yardley, Colin Greaves, Jennie King, Chloe McAdam, Mary Steele, Lisa Price, Adam Streeter, Nigel Charles, Rohini Terry, Douglas Webb, John Campbell, Lucy Hughes, Ben Ainsworth, Ben Jones, Ben Jane, Jo Erwin, Paul Little, Anthony Woolf and Chris Cavanagh*





# Adding web-based behavioural support to exercise referral schemes for inactive adults with chronic health conditions: the e-coachER RCT

Adrian H Taylor<sup>1\*</sup>, Rod S Taylor<sup>2,3</sup>, Wendy M Ingram<sup>1</sup>, Nana Anokye<sup>4</sup>, Sarah Dean<sup>2</sup>, Kate Jolly<sup>5</sup>, Nanette Mutrie<sup>6</sup>, Jeffrey Lambert<sup>2,7</sup>, Lucy Yardley<sup>8,9</sup>, Colin Greaves<sup>2,10</sup>, Jennie King<sup>1</sup>, Chloe McAdam<sup>6</sup>, Mary Steele<sup>9</sup>, Lisa Price<sup>2</sup>, Adam Streeter<sup>1</sup>, Nigel Charles<sup>†</sup>, Rohini Terry<sup>2</sup>, Douglas Webb<sup>1,11</sup>, John Campbell<sup>2</sup>, Lucy Hughes<sup>5</sup>, Ben Ainsworth<sup>9,12</sup>, Ben Jones<sup>1</sup>, Ben Jane<sup>13</sup>, Jo Erwin<sup>14</sup>, Paul Little<sup>9</sup>, Anthony Woolf<sup>14</sup> and Chris Cavanagh<sup>15</sup>

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# Abstract

## Adding web-based behavioural support to exercise referral schemes for inactive adults with chronic health conditions: the e-coachER RCT

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†In memoriam

**Background:** There is modest evidence that exercise referral schemes increase physical activity in inactive individuals with chronic health conditions. There is a need to identify additional ways to improve the effects of exercise referral schemes on long-term physical activity.

**Objectives:** To determine if adding the e-coachER intervention to exercise referral schemes is more clinically effective and cost-effective in increasing physical activity after 1 year than usual exercise referral schemes.

**Design:** A pragmatic, multicentre, two-arm randomised controlled trial, with a mixed-methods process evaluation and health economic analysis. Participants were allocated in a 1 : 1 ratio to either exercise referral schemes plus e-coachER (intervention) or exercise referral schemes alone (control).

**Setting:** Patients were referred to exercise referral schemes in Plymouth, Birmingham and Glasgow.

**Participants:** There were 450 participants aged 16–74 years, with a body mass index of 30–40 kg/m<sup>2</sup>, with hypertension, prediabetes, type 2 diabetes, lower limb osteoarthritis or a current/recent history of treatment for depression, who were also inactive, contactable via e-mail and internet users.

**Intervention:** e-coachER was designed to augment exercise referral schemes. Participants received a pedometer and fridge magnet with physical activity recording sheets, and a user guide to access the web-based support in the form of seven 'steps to health'. e-coachER aimed to build the use of behavioural skills (e.g. self-monitoring) while strengthening favourable beliefs in the importance of physical activity, competence, autonomy in physical activity choices and relatedness. All participants were referred to a standard exercise referral scheme.

**Primary outcome measure:** Minutes of moderate and vigorous physical activity in  $\geq 10$ -minute bouts measured by an accelerometer over 1 week at 12 months, worn  $\geq 16$  hours per day for  $\geq 4$  days including  $\geq 1$  weekend day.

**Secondary outcomes:** Other accelerometer-derived physical activity measures, self-reported physical activity, exercise referral scheme attendance and EuroQol-5 Dimensions, five-level version, and Hospital Anxiety and Depression Scale scores were collected at 4 and 12 months post randomisation.

**Results:** Participants had a mean body mass index of 32.6 (standard deviation) 4.4 kg/m<sup>2</sup>, were referred primarily for weight loss and were mostly confident self-rated information technology users. Primary outcome analysis involving those with usable data showed a weak indicative effect in favour of the intervention group ( $n = 108$ ) compared with the control group ( $n = 124$ ); 11.8 weekly minutes of moderate and vigorous physical activity (95% confidence interval  $-2.1$  to  $26.0$  minutes;  $p = 0.10$ ). Sixty-four per cent of intervention participants logged on at least once; they gave generally positive feedback on the web-based support. The intervention had no effect on other physical activity outcomes, exercise referral scheme attendance (78% in the control group vs. 75% in the intervention group) or EuroQol-5 Dimensions, five-level version, or Hospital Anxiety and Depression Scale scores, but did enhance a number of process outcomes (i.e. confidence, importance and competence) compared with the control group at 4 months, but not at 12 months. At 12 months, the intervention group incurred an additional mean cost of £439 (95% confidence interval  $-\text{£}182$  to  $\text{£}1060$ ) compared with the control group, but generated more quality-adjusted life-years (mean 0.026, 95% confidence interval 0.013 to 0.040), with an incremental cost-effectiveness ratio of an additional £16,885 per quality-adjusted life-year.

**Limitations:** A significant proportion (46%) of participants were not included in the primary analysis because of study withdrawal and insufficient device wear-time, so the results must be interpreted with caution. The regression model fit for the primary outcome was poor because of the considerable proportion of participants [142/243 (58%)] who recorded no instances of  $\geq 10$ -minute bouts of moderate and vigorous physical activity at 12 months post randomisation.

**Future work:** The design and rigorous evaluation of cost-effective and scalable ways to increase exercise referral scheme uptake and maintenance of moderate and vigorous physical activity are needed among patients with chronic conditions.

**Conclusions:** Adding e-coachER to usual exercise referral schemes had only a weak indicative effect on long-term rigorously defined, objectively assessed moderate and vigorous physical activity. The provision of the e-coachER support package led to an additional cost and has a 63% probability of being cost-effective based on the UK threshold of £30,000 per quality-adjusted life-year. The intervention did improve some process outcomes as specified in our logic model.

**Trial registration:** Current Controlled Trials ISRCTN15644451.

**Funding:** This project was funded by the National Institute for Health Research (NIHR) Health Technology Assessment programme and will be published in full in *Health Technology Assessment*; Vol. 24, No. 63. See the NIHR Journals Library website for further project information.

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# List of supplementary material

**Report Supplementary Material 1** Participant information sheet

**Report Supplementary Material 2** Participant consent form

**Report Supplementary Material 3** Movement sensor participant instruction sheet

**Report Supplementary Material 4** Questionnaire booklet: 12 months

Supplementary material can be found on the NIHR Journals Library report page (<http://doi.org/10.3310/hta24630>).

Supplementary material has been provided by the authors to support the report and any files provided at submission will have been seen by peer reviewers, but not extensively reviewed. Any supplementary material provided at a later stage in the process may not have been peer reviewed.



# List of abbreviations

A&E	accident and emergency	IT	information technology
AE	adverse event	ITT	intention to treat
BMI	body mass index	MedDRA	Medical Dictionary for Regulatory Activities
CACE	complier-average causal effect	MVPA	moderate and vigorous physical activity
CI	confidence interval	PA	physical activity
CONSORT	Consolidated Standards of Reporting Trials	PenCTU	Peninsula Clinical Trials Unit
CRF	case report form	PPI	patient and public involvement
CRN	Clinical Research Network	QALY	quality-adjusted life-year
CTU	clinical trials unit	RCT	randomised controlled trial
DMC	Data Monitoring Committee	REC	Research Ethics Committee
EQ-5D-5L	EuroQol-5 Dimensions, five-level version	SAE	serious adverse event
ERS	exercise referral scheme	SD	standard deviation
GP	general practitioner	SF-12	Short Form questionnaire-12 items
GPPAQ	General Practice Physical Activity Questionnaire	SMART	specific, measurable, achievable, relevant, time-bound
HADS	Hospital Anxiety and Depression Scale	TSC	Trial Steering Committee
ICER	incremental cost-effectiveness ratio		



## Plain English summary

When health-care professionals refer patients with chronic conditions to an exercise referral scheme, the effects on long-term increases in physical activity are limited. We therefore developed the e-coachER support package to add to usual exercise referral schemes and to prompt the use of skills such as self-monitoring and goal-setting. This package was also intended to empower patients to increase their levels of physical activity long term. The seven-step programme was delivered online (via an interactive website). As part of the package, we mailed participants a guide for accessing the online programme, a pedometer and a fridge magnet with a notepad to record physical activity. We aimed to determine whether or not adding the e-coachER support to usual exercise referral schemes resulted in lasting changes in moderate and vigorous physical activity and whether or not it offers good value for money compared with exercise referral schemes alone.

A total of 450 inactive individuals were recruited across Plymouth, Birmingham and Glasgow and were referred to an exercise referral scheme for the following participant-reported main reasons: weight loss (50%), low mood (19%), osteoarthritis (12%), type 2 diabetes (10%) and high blood pressure (8%).

Half of the individuals were given access to the e-coachER support and the other half were not. All individuals were mailed a wrist-worn movement sensor (accelerometer) to wear for 1 week and a survey to assess other outcomes at the start of the study as well as at 4 and 12 months post randomisation.

At the start of the study, the participants were inactive and most had multiple health conditions. The participants had an average body mass index of 33 kg/m<sup>2</sup> and an average age of 50 years. Most (83%) were white.

Participants with access to e-coachER support were only slightly more active at 12 months than those who did not have access, but we cannot be confident in the findings because we had data from fewer participants than planned. The lack of a clear effect may have been as a result of around one-third of participants not accessing the website, but otherwise there was reasonable engagement. The provision of the e-coachER support package led to an additional cost of £439 per participant over a 12-month period.





# Scientific summary

## Background

From meta-analyses of randomised trials, there is evidence that primary care exercise referral schemes result in a modest increase in the proportion of participants achieving 90–150 minutes of self-reported moderate and vigorous physical activity at least 6 months after randomisation, compared with usual care. Rigorous research is needed to assess the clinical effectiveness and cost-effectiveness of new approaches to increase exercise referral scheme uptake, adherence and change in long-term objectively assessed moderate and vigorous physical activity among inactive patients with chronic conditions.

E-health interventions for promoting physical activity have become popular because they offer an opportunity to target a wide range of people at a low cost, but to our knowledge no studies have explored their use alongside exercise referral schemes that offer face-to-face support. We developed a bespoke support system, using the LifeGuide© (LifeGuide version 1.0.7.30, University of Southampton, Southampton, UK) platform, to empower exercise referral scheme patients with physical and mental health conditions to become more physically active and remain motivated to do so. Building on self-determination theory as a framework, we incorporated evidence-based components into a 'seven steps to health' web-based programme called e-coachER, with support available for up to 12 months. At the same time as an exercise referral, participants were mailed a free pedometer, a fridge magnet with attached tear-off strips to record daily steps or minutes of moderate and vigorous physical activity, and a user guide with instructions on how to access the web-based support. The e-coachER 'seven steps to health' programme aimed to increase favourable beliefs in the importance of being physically active, confidence in being regularly physically active, being autonomous in choosing what, where and when to be active, and finding and using support to be physically active, whether that be face to face in the exercise referral schemes, with friends and family or online. We defined getting to step 5 (setting a goal and reviewing a goal online) as a sufficient 'dose' of the intervention to have an impact on minutes of moderate and vigorous physical activity, although we recognised that mailing a pedometer could be an effective intervention alone.

## Objectives

The overall aim of the study was to determine whether or not adding the e-coachER intervention to usual exercise referral schemes was more effective and cost-effective in increasing physical activity after 1 year, compared with usual exercise referral schemes alone.

## Research questions

The specific research questions were:

- Does the e-coachER intervention, when added to usual exercise referral schemes, compared with usual exercise referral schemes alone, increase the total minutes of accelerometer-assessed moderate and vigorous physical activity (in bouts of at least 10 minutes) per week at 12 months post randomisation?

- Does the e-coachER intervention, when added to usual exercise referral schemes, compared with usual exercise referral schemes alone, improve:
  - exercise referral scheme attendance?
  - other accelerometer- and self-reported measures of moderate and vigorous physical activity?
  - quality of life and mental health?
  - process outcomes (e.g. confidence to do and importance of doing physical activity, a sense of autonomy in deciding what physical activity to do and when, a sense of relatedness to others in doing physical activity, and use of self-monitoring and goal-setting)?
- Is the e-coachER intervention, when added to usual exercise referral schemes, compared with usual exercise referral schemes alone, cost-effective?
- Is the effect of the intervention moderated by participant and exercise referral scheme characteristics?
- What are the mechanisms through which the intervention has an impact on the outcomes?

## Methods

The study involved an individually randomised, pragmatic, multicentre, two-arm randomised controlled trial with follow-up at 4 and 12 months, with an embedded mixed-methods process evaluation and health economic analysis. Patients were referred to a local exercise referral scheme in the UK cities of Plymouth, Birmingham and Glasgow, and invited to join the study by primary care or exercise practitioners. To maximise the generalisability of the findings, recruitment sites were chosen to reflect a range of cultural and contextual factors, including the way in which exercise referral schemes operated.

Participants were aged 16–74 years with a body mass index of 30–40 kg/m<sup>2</sup> and had one or more of the following conditions: hypertension, prediabetes, type 2 diabetes, lower limb osteoarthritis and a current or recent history of treatment for depression. Participants were eligible if they were inactive or moderately inactive (using the General Practice Physical Activity Questionnaire) and were an internet user contactable via e-mail.

The primary outcome was minutes of moderate and vigorous physical activity in  $\geq 10$ -minute bouts measured by accelerometer over 1 week at 12 months, worn  $\geq 16$  hours per day for  $\geq 4$  days including  $\geq 1$  weekend day. Other accelerometer-derived physical activity measures (e.g. not in  $\geq 10$ -minute bouts), self-reported physical activity (7-day recall of physical activity), exercise referral scheme attendance (at initial session with exercise referral scheme practitioner), non-validated process measure survey items and EuroQol-5 Dimensions, five-level version, and Hospital Anxiety and Depression Scale scores were collected at baseline, and then at 4 and 12 months.

## Results

The sample ( $n = 450$ ) had a mean body mass index of 32.6 kg/m<sup>2</sup> (standard deviation 4.4 kg/m<sup>2</sup>), and the primary participant-reported reasons for referral to the exercise referral schemes were weight loss (50%), low mood (19%), osteoarthritis (12%), type 2 diabetes (10%) and high blood pressure (8%). Participants identified additional reasons for referral, which were weight loss (81%), low mood (54%), osteoarthritis (24%), type 2 diabetes (26%) and high blood pressure (33%), which indicated the high degree of comorbidity in the sample. At baseline, only 4% of the sample achieved  $\geq 150$  minutes of moderate and vigorous physical activity (accumulated in bouts of  $\geq 10$  minutes) for 1 week at 12 months post randomisation.

## Primary analysis

Loss to follow-up and incomplete data reduced the sample size to 232 participants for the primary analysis (intervention,  $n = 108$ ; control,  $n = 124$ ). Intention-to-treat, complete-case-adjusted comparison of groups at 12 months showed a weak indicative effect in favour of the intervention group ( $n = 232$ ; mean difference 11.8 minutes per week, 95% confidence interval  $-2.1$  to  $26.0$  minutes;  $p = 0.10$ ). Because of the large proportion of participants who had zero values for the primary outcome, five different statistical models were run in the primary analysis and only one showed a significant ( $p < 0.01$ ) effect in favour of the intervention. A secondary analysis showed that with only those with complete data at baseline and 4 and 12 months, there was also no significant effect. In further sensitivity analyses of the primary outcome, with less rigorous criteria applied to including participants with four different wear-time completion thresholds (i.e.  $\geq 4$  days regardless of whether weekday or weekend day for  $\geq 16$  hours per day;  $\geq 4$  days regardless of weekend or weekday for  $\geq 10$  hours per day;  $\geq 4$  days including 1 weekend day for  $\geq 10$  hours per day;  $\geq 4$  days including 1 weekend day for  $\geq 10$  hours per day and weighted by number of days of valid wear), there remained no significant between-group differences. A complier-average causal effect analysis, with consideration of whether or not participants had completed an a priori definition of adequate intervention dose (i.e. step 5: completed at least one goal review in e-coachER), also revealed no intervention effect.

The results of the primary analysis were not influenced by age, gender, trial site, participants' reported main chronic condition for referral or information technology literacy level.

In exploratory analysis of  $\geq 10$ -minute bouts of accelerometer data, with only participants who were included in the intention-to-treat, complete-case-adjusted analysis, the control group showed a significant mean (standard deviation) increase of 8.2 (32.1) minutes of moderate and vigorous physical activity from baseline to 4 months, but a non-significant decline from baseline to 12 months. The intervention group did not change from baseline to either 4- or 12-month assessment.

## Secondary analysis

Applying the same approach as in the primary analysis, there were no between-group differences at 12 months in any of the other accelerometer-derived or self-reported moderate and vigorous physical activity outcomes, with one exception. In an intention-to-treat imputed comparison at 12 months participants in the intervention group were more likely than the control group to self-report that they had achieved 150 minutes of weekly moderate and vigorous physical activity (odds ratio 1.55, 95% confidence interval 0.99 to 2.42;  $p = 0.05$ ). The intervention had no effect on exercise referral scheme attendance: in the control group, 78% of the 223 participants for whom we had exercise referral scheme attendance data attended the exercise referral scheme at least once, compared with 167 (75%) of 223 in the intervention group. The intervention also had no effect on EuroQol-5 Dimensions, five-level version, or Hospital Anxiety and Depression Scale scores at 12 months compared with the control group. In an intention-to-treat imputed comparison at 12 months, the intervention group had lower Hospital Anxiety and Depression Scale depression and anxiety scores than the control group.

## Intervention engagement

Among the intervention participants, 64% logged onto the online support at least once, with generally positive feedback on its value. The mean (standard deviation) number of goal reviews was 2.5 (4.5) with a range of 0–24 reviews. The 144 participants who registered logged onto the online support for a mean (standard deviation) and median number of times of 14.1 (16.7) and 6, respectively, with a range of 1–101.

Of the 81 (36%) participants who completed a goal review, the mean (standard deviation) and median number of reviews was 14.4 (13.8) and 4.5, respectively, with a range of 1–52. Overall, participants who registered online spent a mean (standard deviation) of 6.47 (7.45) minutes and a median of 4.08 minutes each time they logged into the e-coachER website. The engagement data from the LifeGuide platform indicate that reasonable levels of engagement were achieved. The analysis of qualitative data from 38 interviews with 26 participants suggests a generally positive assessment of the content and functionality of e-coachER as a valuable resource, although some people identified limitations and made recommendations for improvements.

## Process outcomes

Our logic model predicted that e-coachER engagement would strengthen various beliefs that would, in turn, translate into increases in moderate and vigorous physical activity, compared with usual exercise referral scheme support. Among the participants included in only the primary analysis, the intervention did increase the following up to 4 months, but not 12 months, compared with the control group: perceived importance of doing at least 30 minutes of moderate-intensity physical activity (e.g. brisk walk) on at least 5 days per week; confidence in achieving at least 30 minutes of moderate-intensity physical activity on at least 5 days per week; and perceived competence in being regularly physically active. Changes (from baseline to 4 months) in these process outcomes did not mediate changes in the primary outcome at 12 months.

## Health economics

The e-coachER intervention incurred an additional mean cost of £439 (95% confidence interval –£182 to £1060) (from additional service use and intervention delivery) and, compared with exercise referral schemes alone, generated a small increase in quality-adjusted life-years (mean 0.026, 95% confidence interval 0.013 to 0.040) over 12 months, with an incremental cost-effectiveness ratio of £16,885 per quality-adjusted life-year.

## Conclusion

We believe this to be the most rigorous study to date on the clinical effectiveness and cost-effectiveness of adding web-based behavioural support to usual exercise referral schemes. Adding the e-coachER intervention to usual exercise referral schemes led to only a weak indicative effect on objectively assessed moderate and vigorous physical activity at 1 year post randomisation. Given this result and the small numbers analysed, the findings must be interpreted with caution. The e-coachER intervention had little or no benefit on other physical activity measures of moderate and vigorous physical activity, health-related quality of life or mental health. We explored a number of ways of analysing the data, and the findings were consistent. However, the cost of the e-coachER intervention and the gains (albeit small) in quality-adjusted life-years indicate that e-coachER has a probability of 63% to be a cost-effective intervention at the National Institute for Health and Care Excellence's willingness-to-pay threshold of £30,000 per quality-adjusted life-year. The intervention did improve some process outcomes as specified in our logic model, but changes in perceived importance, confidence and competence associated with being physically active from baseline to 4 months did not mediate intervention effects on the primary outcome.

## Implications for health care

Our findings suggest that clinically meaningful increases in physical activity may not be derived from the e-coachER intervention, but given its additional cost and associated small gains in quality-adjusted life-years (main outcome for the economic evaluation), that such an intervention could still be a cost-effective addition to usual exercise referral schemes (offered in different ways) for increasing physical activity for up to 12 months. In other words, sending patients a pedometer and a fridge magnet with tear-off physical activity self-monitoring strips, and providing access to a website that requires virtually no human support could be a cost-effective way to improve quality of life in inactive patients with certain chronic conditions. The process evaluation interviews identified a number of ways in which e-coachER could be improved, such as giving patients more information about their specific health conditions. Alternatively, improvements could be made by providing more structured guidance in the user guide on the overall aim and content of web-based e-coachER support, including where to find links to more information about exercise and medical conditions.

## Recommendations for research

The modest engagement in the online e-coachER support suggests that work is needed to understand what factors influenced intervention engagement and how best to further develop low-cost and scalable support to increase exercise referral scheme uptake and maintenance of physical activity. Once this has been done, further research could examine the effects of a modified e-coachER-type intervention for participants with chronic conditions involved in the present study and others (e.g. with cancer, back pain and in cardiac rehabilitation).

The e-coachER study has provided a rich data set that offers the chance to explore additional questions including the following:

- What were the characteristics of participants that predicted changes in 4- and 12-month physical activity?
- How did different measures of moderate and vigorous physical activity (self-report and accelerometer derived) influence the findings, beyond what we present here?
- What other aspects of intervention engagement (derived from the LifeGuide platform) were used, and did any influence changes in process and behavioural outcomes?
- Among subsets of the sample (e.g. those with low mood), what changes in quality of life, depression and anxiety occurred as a result of the intervention versus usual exercise referral schemes?

## Trial registration

This trial is registered as ISRCTN15644451.

## Funding

This project was funded by the National Institute for Health Research (NIHR) Health Technology Assessment programme and will be published in full in *Health Technology Assessment*; Vol. 24, No. 63. See the NIHR Journals Library website for further project information.



# Chapter 1 Introduction

## Scientific background

As described elsewhere,<sup>1</sup> evidence-based guidelines recommend both aerobic training and strength training for improving health markers and quality of life among those people with common chronic metabolic conditions<sup>1–5</sup> and musculoskeletal conditions.<sup>6</sup> To prevent or reduce depression, mostly aerobic exercise is recommended.<sup>7</sup> Public health guidelines of 150 minutes of moderate activity per week (accumulated in bouts of  $\geq 10$  minutes) or 75 minutes of vigorous activity per week are met by only 66% of men and 58% of women aged  $\geq 19$  years in England,<sup>8</sup> which is similar to results from the Scottish Health Survey 2014<sup>9</sup> (68% men; 59% women), based on self-report data from a national representative survey. The guidelines also highlight the importance of reducing sedentary behaviour and regularly doing bouts of resistance exercise. Physical inactivity, based on data from 2013–14, collected by Clinical Commissioning Groups in the UK, costs the NHS £455M.<sup>10</sup>

Even small increases in physical activity (PA) and reduced sedentary time, especially among the least active,<sup>10</sup> are likely to provide health benefits.<sup>11,12</sup> Patients with obesity, hypertension, type 2 diabetes, osteoarthritis and depression do less PA than the general population<sup>2</sup> and report greater barriers to increased PA.

## Exercise referral schemes in the UK

A variety of approaches have been explored to promote PA within primary care, such as referring patients to 'exercise on prescription' [i.e. an exercise referral scheme (ERS)]. As described previously,<sup>1</sup> in the UK, ERSs have been popular, with an estimated 600 schemes involving up to 100,000 patients per year in 2008.<sup>13</sup> There is currently no single model for ERSs in the UK, but they mainly involve referral to a programme (e.g. 10–12 weeks) of structured, supervised exercise at an exercise facility (e.g. gym or leisure centre) or a counselling (and signposting) approach to support patients to engage in a variety of types of PA.<sup>13</sup> ERSs operate diversely to accommodate patient choice and local availability of facilities, the common goal being to reduce the risk of long-term metabolic, musculoskeletal and mental health conditions due to physical inactivity.

Evidence from a meta-analysis of eight randomised controlled trials (RCTs) involving 5190 participants eligible for ERSs<sup>14</sup> indicated only a small increase in the proportion of participants who achieved 90–150 minutes of PA of at least moderate intensity per week, compared with no exercise control, at the 6- to 12-month follow-up among at-risk individuals. However, uncertainty remains regarding the effects for patients with specific medical conditions, no study assessed long-term PA objectively and many of the eight studies reviewed had relatively small sample sizes.

A review<sup>15</sup> reported that the average ERS uptake (attendance at the first ERS session) ranged from 66% in observational studies to 81% in RCTs, and average levels of 'adherence' ranged from 49% in observational studies to 43% in RCTs. Predictors of uptake and adherence have been explored; women were more likely than men to begin an ERS, but less likely to adhere to it, and older people were more likely to begin and adhere to an ERS.<sup>15</sup> As an example of a large observational retrospective study,<sup>16</sup> of 6894 participants who had attended an ERS over 6 years, 37.8% ( $n = 2608$ ) dropped out within 6 weeks and 50.03% ( $n = 3449$ ) dropped out by the (final) 12th week, and males ( $p < 0.001$ ) and older people ( $p < 0.001$ ) were more likely to adhere than females and younger people, respectively. ERSs may help patients to become familiar with medical conditions<sup>17</sup> and target key processes of behaviour change. However, the following features of an ERS may reduce uptake and adherence: inconvenience, cost, limited sustainable PA support (e.g. for 10 weeks) and low appeal for structured exercise and/or the medical



model (i.e. 'exercise on prescription'), which may in some schemes do little to provide autonomous support or empower patients to develop self-determined behaviour to manage chronic medical conditions.<sup>13,18,19</sup>

It therefore appears that additional support may be needed that is accessible and is low cost, can be tailored to support a wide range of individual needs and empowers patients to develop and use self-regulatory skills (e.g. self-monitoring, goal-setting) to self-manage their chronic conditions. In one study, training for ERS staff to foster self-determined behaviour increased PA more than when the ERS was delivered by untrained staff at 3 and 6 months.<sup>20</sup> Similarly, training of ERS staff in behaviour change techniques and motivational interviewing led to small additional changes in self-reported PA after 12 months<sup>17</sup> compared with no ERS. Challenges in training staff across a wide geographical area across Wales and monitoring intervention fidelity were noted.

### Intervention technologies to promote physical activity

To address the challenges with face-to-face promotion of PA noted above and to encompass the growing use and availability of new technologies, a wide variety of online and mobile support has been developed and used to promote PA.

As described previously,<sup>1</sup> there is growing evidence on the effectiveness of technology-based interventions for promotion of PA.<sup>21,22</sup> Studies include a wide range of interventions (from quite simple self-monitoring to interventions with multiple complex behaviour change components), targeted at different clinical groups with different baseline levels of PA, with various PA outcomes reported (very few using objective measures), and with mostly short-term follow-ups. In addition, some comparisons are between intervention versus no intervention and others are versus human contact, although none reports on the effects of adding web-based support to complement face-to-face support provided by ERSs. The impact of web-based and technology interventions on increasing PA is small to moderate (effect size  $\leq 0.4$ ). However, there is evidence from more rigorous studies that interventions with more behaviour change components and ones targeting less active populations are more effective.<sup>21,22</sup> A systematic review<sup>23</sup> highlighted the importance of maximising sustained engagement in web-based interventions for enhancing change in the target behaviour. A recent study<sup>24</sup> highlighted that self-monitoring of PA and tailored feedback were important to increase engagement, and periodic communications helped to maintain participant engagement.

The LifeGuide© (version 1.0.7.30, University of Southampton, Southampton, UK; [www.LifeGuideonline.org/](http://www.LifeGuideonline.org/); accessed 25 February 2020) platform has been extensively used to develop and evaluate the acceptability and impact of online behaviour change and self-management interventions with a variety of clinical groups, including in primary care.<sup>25-27</sup> As an example, when adding online LifeGuide support to face-to-face support there was a greater lasting reduction in obesity than with face-to-face dietetic advice alone.<sup>28</sup> The LifeGuide platform provides a researcher-led tool to develop theory-driven interventions and evidence of the effectiveness of techniques.<sup>29,30</sup> It also provides the opportunity to capture intervention engagement and assess the utility of different behaviour change components.

### The potential for e-coachER

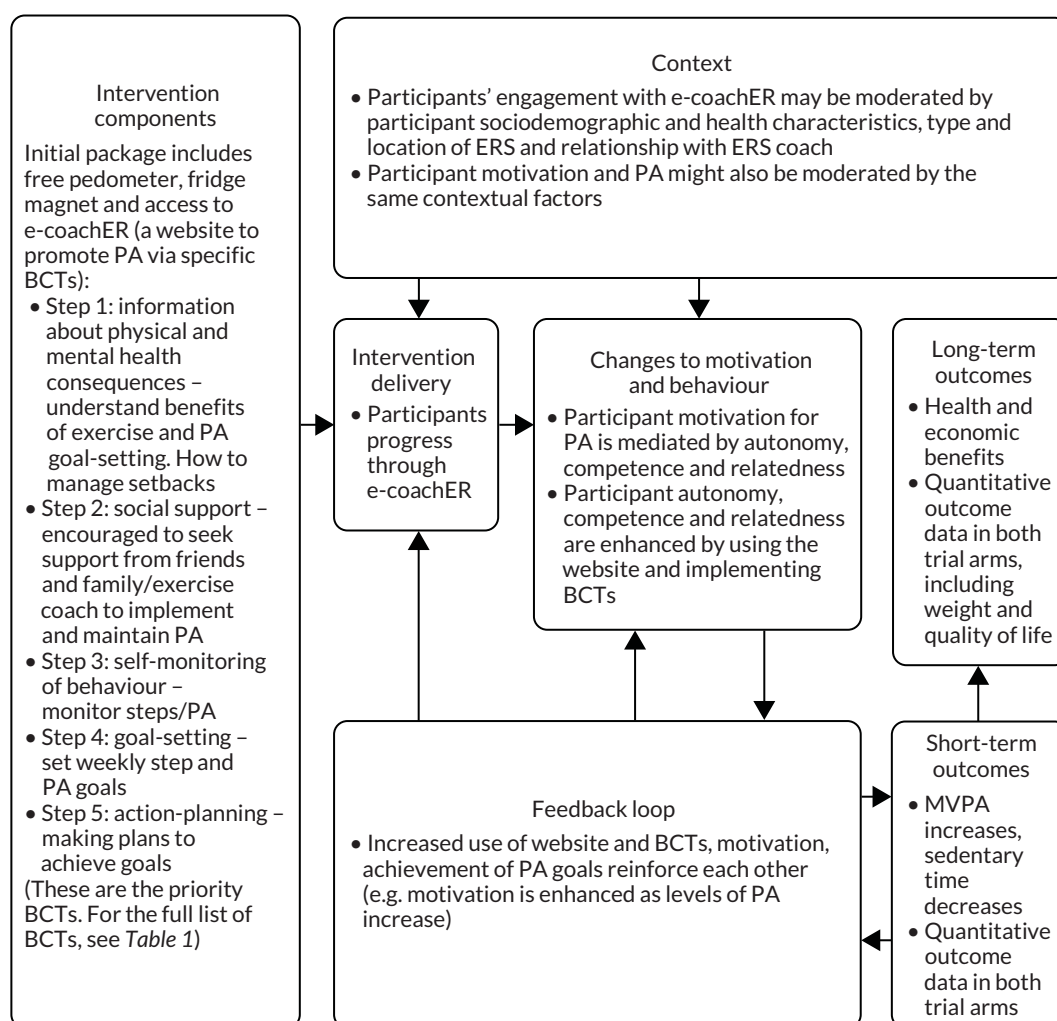
Following iterative development work and user group testing and involvement, drawing on some online modules used in other LifeGuide interventions, for example in secondary prevention of coronary heart disease,<sup>25</sup> we developed a bespoke intervention. We called the intervention 'e-coachER' and it was designed to support patients with chronic physical and mental health conditions who have been referred from primary care to an ERS to receive face-to-face support.<sup>1</sup> The overarching aim of the e-coachER intervention was to facilitate long-term PA by promotion of evidence-based self-regulatory skills and to encourage interaction with others (including the ERS professional, family and friends), and founded on self-determination theory<sup>31</sup> to build a sense of competence in managing PA, autonomy or control over PA,

and connection or relatedness with others. We wanted to encourage uptake and adherence to the ERS but if that was not acceptable or feasible for participants then we offered support to find alternative ways to be physically active in a way that may support their needs as someone who was inactive. It was also important that the intervention could be scaled up to promote PA for patients with obesity, hypertension, type 2 diabetes, osteoarthritis and risk of depression at probably low cost<sup>32,33</sup> and also potentially make it available for patients with other chronic medical conditions (e.g. low back pain, heart disease and cancer).

## Developing the e-coachER intervention

The intervention development included the piloting of the welcome pack and development of an initial version of e-coachER, built on wide-ranging experiences from the development of other self-management interventions using the LifeGuide platform<sup>34</sup> and beta testing over 7 months. Co-applicants and researchers then provided feedback on a time-truncated version, and ERS users provided feedback on a real-time version for 5 months before the website was locked for the RCT.

The development of all components of the e-coachER intervention followed a logic model as shown in Figure 1.<sup>1</sup>



**FIGURE 1** Logic model for the e-coachER intervention. BCT, behaviour change technique; MVPA, moderate and vigorous physical activity. Reproduced with permission from Ingram *et al.*<sup>1</sup> This is an Open Access article distributed in accordance with the terms of the Creative Commons Attribution (CC BY 4.0) license, which permits others to distribute, remix, adapt and build upon this work, for commercial use, provided the original work is properly cited. See: <http://creativecommons.org/licenses/by/4.0/>. The figure includes minor additions and formatting changes to the original text.

The key components of e-coachER include the following:

- On allocation to the intervention, all participants received a 'welcome pack' (Figure 2) that contained a user guide and the participant's unique user log-in and registration details to access the e-coachER website, a simple pedometer (step counter) with instruction sheet and a fridge magnet with tear-off sheets to record daily PA (complete with trial branding and e-coachER helpline number). Participants were encouraged to use the pedometer and the PA record sheets for self-monitoring and goal-setting in conjunction with the website.
- The e-coachER support system, hosted on the LifeGuide platform, provided support through seven 'steps to health' lasting approximately 5–10 minutes each, as shown in Table 1.
- The steps were designed to do the following: encourage participants to think about the benefits of PA (motivation); seek support from an ERS practitioner, friends/family and the internet (support/relatedness); set progressive goals; self-monitor PA with a pedometer and upload step counts or minutes of moderate and vigorous physical activity (MVPA) (self-regulation, building confidence/autonomy); and find ways to increase PA more sustainably in the context of day-to-day life and deal with setbacks (building confidence). The sequential content, objectives and how this was implemented were mapped against a taxonomy for behaviour change techniques shown in Table 1.<sup>35</sup> The website content is illustrated in Appendix 1.
- Participants were encouraged to use e-coachER support as an interactive tool by using pre-set or personally set reminders to upload step counts or minutes of MVPA, and messages of encouragement. A lack of engagement (e.g. not reviewing a goal by entering step counts 1 week later, or not signing into the website for 1, 2 and 4 weeks) triggered reminder e-mails. Participants were reminded by prompts to review goals the next day.
- An avatar was used throughout the content to avoid having to represent a range of individual characteristics, such as age, gender and ethnicity. The avatar delivered brief narratives to normalise and support behaviour change and encourage the use of e-coachER. Automatic and user-defined e-mails generated by the LifeGuide system promoted ongoing use of functions such as recording weekly PA and goal-setting. Participants were provided with links to reputable generic websites for further information about the chronic conditions of interest and lifestyle, links to other websites and apps (applications) for self-monitoring health behaviour and health, as well as modifiable listings of local opportunities to engage in PA.
- The only webpages that were not 'locked' after the initial participant began the intervention were pages for the respective recruitment sites that displayed links to the following websites: (1) local community opportunities for engaging in PA, (2) disease-specific (e.g. Diabetes UK, Royal College of Psychiatrists) informational sites about the role of PA in preventing and managing the condition, and (3) sites about other methods to optimise ways to be physically active (e.g. more sophisticated technologies to self-monitor).
- Our aim was to maximise accessibility and use. Therefore, a local researcher provided technical support if requested, but did not support behaviour change directly. If participants did not register on the e-coachER website within the first few weeks, they were followed up with a telephone call to offer support to use e-coachER. If technical support to resolve any user operational issues with the website (e.g. re-issuing passwords) was needed, participants were referred to a centralised technician within the LifeGuide team for further support.

## Trial aim and objectives

The overarching aim was to determine if e-coachER online support combined with usual ERS provided a clinically effective and cost-effective approach to supporting increases in PA in people referred to an ERS with a range of chronic conditions.



**FIGURE 2** The e-coachER welcome pack. The welcome pack comprises a user guide, pedometer and magnet notepad for recording PA.

**TABLE 1** Sequential components of the e-coachER intervention and objectives mapped against behaviour change techniques, and explanation of the implementation strategy

Sequential components	Objectives	<sup>a</sup> Behaviour change techniques <sup>35</sup>	Implementation strategy
Welcome pack and pedometer and an introduction to web-based support for self-directed PA	<p>To introduce the user to the philosophy of the website to become personal coach</p> <p>Build on personal support provided by ERS using web-based platform</p> <p>Support those who do not want to/cannot engage with ERS personnel</p> <p>Support achievement of personal goals for PA to enhance health</p>	10. Self-monitoring	<p>Explain philosophy of using website to become own personal coach</p> <p>Links provided to local services and other self-help resources to highlight patient autonomy and choice</p> <p>Offers e-coachER facilitator to help with using technology. Provide link to IT support in Southampton</p>
Step 1: thinking about the benefits of PA	Elevate importance of PA	<p>82. Information about health consequences</p> <p>83. Information about emotional consequences</p>	<p>Quiz to engage participants using positive framing</p> <p>Provide evidence of multiple benefits of PA especially for relevant health condition(s)</p> <p>Elicit and address concerns about PA, describing support given as part of ERS and by website</p>
Step 2: support to get active	To encourage user to access and create social support networks	1. Social support (practical)	Explain how to make the most of the ERS support to learn how to become own personal trainer in future

continued

**TABLE 1** Sequential components of the e-coachER intervention and objectives mapped against behaviour change techniques, and explanation of the implementation strategy (*continued*)

Sequential components	Objectives	<sup>a</sup> Behaviour change techniques <sup>35</sup>	Implementation strategy
	To encourage user to take advantage of ERS and face-to-face support offered	2. Social support (emotional)	Explain how user can create a personal 'PA challenge' and share it with family, friends, peers, and exercise and health professionals. The patient may be encouraged to tell others about how e-coachER has been used to support behaviour change
		3. Social support (unspecified)	Suggest ways of involving family or friends in longer-term support for continued PA  Link to online sources of local support (e.g. local walking or jogging group, or British Trust for Conservation Volunteers)  How to use website to send personalised e-mail/text reminders, motivational messages to self  Draw on positive normative beliefs; identify benefits of social interaction (companionship). Sharing personal PA challenge with others, involve friends and family, online local support links  Identify benefits of informational support (from ERS) in addition to emotional support from family and friends)
Step 3: counting your steps	To encourage and support the user to monitor step counts using a pedometer over 1 week  Emphasise personal experimentation	10. Self-monitoring of behaviour	Provide guidance on how to count steps/use pedometer  Provide guidance on how steps can be implemented into lifestyle  Encourage self-monitoring using diary
Step 4: making your step plans	To set explicit step count goals for the following week	66. Goal-setting (behaviour)	Give rationale and evidence for goal-setting for graded increase in PA  User sets specific, achievable goals for next week (e.g. sessions completed, step count using the supplied pedometers)  Links provided to local services and other resources

**TABLE 1** Sequential components of the e-coachER intervention and objectives mapped against behaviour change techniques, and explanation of the implementation strategy (*continued*)

Sequential components	Objectives	<sup>a</sup> Behaviour change techniques <sup>35</sup>	Implementation strategy
Step 5: making your activity plans	To encourage and support the user to identify behavioural goals (types of activities)	68. Action-planning	User selects walking or 'other physical activities' (which include options for facility-based activity with practitioner support within ERS)  Present options for facility and lifestyle-based activity  Sets specific, achievable goals for next week with a particular focus on avoiding days with less activity by planning walking or other activities  Keeping a PA diary
Weekly goal and PA review	To promote adherence and graded increase in PA by providing tailored feedback and advice based on self-reported goal progress	66. Goal-setting (behaviour)	User records extent to which goals are achieved in previous week, gets progress graph and personalised feedback:
		68. Action-planning	<ul style="list-style-type: none"> <li>• Praise for any goal achievement, encouragement to set a more challenging goal if not yet meeting target PA criteria</li> </ul>
		69. Review behaviour goals	<ul style="list-style-type: none"> <li>• Encouragement where goals not attained, with links to webpages to assist with increasing motivation or confidence, selecting different activities or goals, making better plans, accessing support, overcoming setbacks (with links to relevant sessions below)</li> <li>• Each session completed ends with new links to reputable information and resources (e.g. NHS Choices, condition-specific PA advice websites)</li> <li>• Help user plan gradual increases in PA</li> </ul>
Step 6: finding ways to achieve your plans	To help the user harness their environment to provide support for PA	30. Restructuring the physical environment	Make plan to use environment to automatically support PA (with examples, e.g. fitness equipment in living room, route to work/shops that involves more PA, committing self to specific routine)
continued			

**TABLE 1** Sequential components of the e-coachER intervention and objectives mapped against behaviour change techniques, and explanation of the implementation strategy (*continued*)

Sequential components	Objectives	<sup>a</sup> Behaviour change techniques <sup>35</sup>	Implementation strategy
	Identifying personal motivations, building confidence	31. Restructuring the social environment	Advise user on how to use website to send personalised e-mail/text reminders, motivational messages
		32. Avoidance/reducing exposure to cues for behaviour	Overcoming barriers in work, leisure, home and travel. Building self-efficacy
			Using smartphone apps for mobile support
Motivational messages (text or/and e-mails)	To provide reminders of users' personal reasons (not necessarily health reasons) for becoming more active	15. Prompts/cues	Invite user to identify personal motivations for becoming more active
Step 7: dealing with setbacks	To provide strategies for overcoming relapse in levels of PA	5. Reduce negative emotions	Invite user to write motivational message to be sent weekly or monthly detailing their own motivations for becoming more active
			Identify possible causes of relapse (e.g. illness, holidays, change in work hours, new caring responsibilities) and plan ways to overcome barriers
			Challenging catastrophic negative thoughts about lapses from intended PA
			How to learn from a lapse and plan to avoid or overcome in future
			Provide salient role models of people overcoming barriers to successfully engage with PA

IT, information technology.

<sup>a</sup> The numbers in this column correspond to the behaviour change techniques, which are listed numerically in Michie *et al.*<sup>35</sup> Reproduced with permission from Ingram *et al.*<sup>1</sup> This is an Open Access article distributed in accordance with the terms of the Creative Commons Attribution (CC BY 4.0) license, which permits others to distribute, remix, adapt and build upon this work, for commercial use, provided the original work is properly cited. See: <http://creativecommons.org/licenses/by/4.0/>. The table includes minor additions and formatting changes to the original text.

The specific objectives were to:

- determine whether or not there is an increase in the total weekly minutes of MVPA at 12 months post randomisation in the intervention group compared with the control group
- determine whether or not there is an increase in the proportion of participants in the intervention group compared with the control group who:
  - take up the opportunity to attend an initial consultation with an exercise practitioner
  - maintain objectively assessed PA at 4 and 12 months post randomisation
  - maintain self-reported PA at 4 and 12 months post randomisation
  - have improved health-related quality of life at 4 and 12 months post randomisation



- quantify the additional costs of delivering the intervention, and determine the differences in health utilisation and costs between the intervention and control groups at 12 months post randomisation
- assess the cost-effectiveness of the intervention compared with control at 12 months post randomisation [incremental cost per quality-adjusted life-year (QALY)] using a previously developed decision model to estimate future costs and benefits
- quantitatively and qualitatively explore whether or not the impact of the intervention is moderated by medical condition, age, gender, socioeconomic status, information technology (IT) literacy or ERS characteristics
- quantitatively and qualitatively explore the mechanisms through which the intervention may have an impact on the outcomes, through rigorous mixed-methods process evaluation and mediation analyses (if appropriate).





## Chapter 2 Methods

### Study design

This was a multicentre, parallel, two-arm RCT with participant allocation to usual ERS alone (control) or usual ERS plus web-based behavioural support (intervention) with parallel economic and mixed-methods process evaluations.<sup>1</sup> The trial design is summarised in *Figure 3*, from Ingram *et al.*<sup>1</sup>

Recruitment to the trial took place over a 21-month period (July 2015 to March 2017) in three areas in the UK: Greater Glasgow, West Midlands and South West England (including Plymouth, Cornwall and Mid Devon). The majority of participants lived in urban locations. Further information about the characteristics of the cities involved and the respective ERSs to which participants were referred is given in Ingram *et al.*<sup>1</sup>

### Ethics approval and research governance

Ethics approval for the study was granted by North West Preston NHS Research Ethics Committee (REC) in May 2015 (reference 15/NW/0347). Approval for activity at non-NHS sites was obtained from the same REC for the following ERSs: Everyone Active (Plymouth), Teignbridge District Council (Cornwall), Tempus Leisure (Cornwall), Be Active Plus (West Midlands) and Live Active (Glasgow) in December 2015, and Docspot (West Midlands) in November 2016.

NHS Research and Development approval was granted by the Royal Devon and Exeter NHS Foundation Trust Shared Management Service for the Plymouth site (July 2015); NIHR Clinical Research Network (CRN) West Midlands for the Birmingham site (July 2015); and the NHS Greater Glasgow and Clyde Health Board for the Glasgow site (January 2016).

Prior to commencing recruitment, the trial was registered with the International Standard Randomised Controlled Trial Number Register (ISRCTN) under reference number 16900744 and NIHR CRN Portfolio 19047. A summary of the changes made to the original protocol is given later in this chapter.

### Patient and public involvement

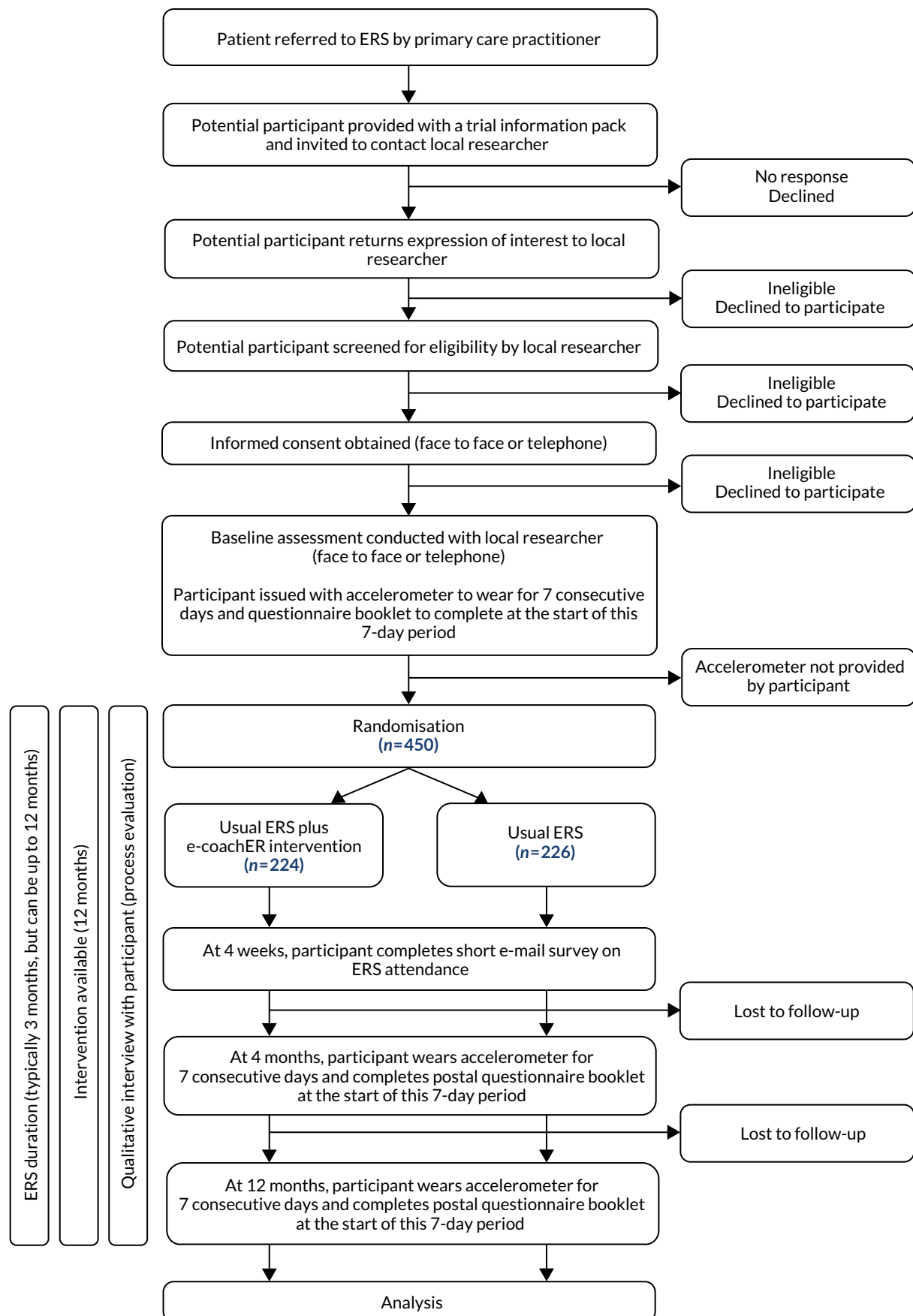
#### Aim

The aim was to involve public representatives throughout the study to ensure that the intervention and trial methods were appropriate for the target population.

#### Methods

The target trial population was composed of patients with one or more physical and mental health conditions; there was no single patient support group or user group that could be invited to contribute as patient and public involvement (PPI) representatives. Hence, PPI representatives with diverse clinical conditions were sought from an ERS provider in Plymouth. Others involved in the delivery of ERSs as managers or practitioners were also consulted to ensure that the methods and intervention were aligned with the usual ERS, especially in the recruitment locations.

There was comprehensive PPI in intervention development. PPI representatives provided critical feedback in informal focus groups on the e-coachER website and registration processes, and on the use of the pedometer and the fridge magnet (with recording strips) as a motivational tool in the e-coachER support package.



**FIGURE 3** Participant pathway. Reproduced with permission from Ingram *et al.*<sup>1</sup> This is an Open Access article distributed in accordance with the terms of the Creative Commons Attribution (CC BY 4.0) license, which permits others to distribute, remix, adapt and build upon this work, for commercial use, provided the original work is properly cited. See: <http://creativecommons.org/licenses/by/4.0/>. The figure includes minor additions and formatting changes to the original text.

Patient and public involvement representatives with experience of ERSs also contributed to the study via their membership of the e-coachER Project Management Group and Trial Steering Committee (TSC).

## Results

Notable benefits included having access to PPI representatives' perspectives on (1) participant-facing documents, such as the e-coachER invitation materials and participant newsletter, (2) usability of the e-coachER intervention package and (3) suggestions to overcome barriers to recruitment.

## Discussion

One PPI representative was influential with regard to including a 'personal message' from an ERS user in the periodic participant newsletter, the aim being to convey the importance and value of taking part in the study from the perspective of someone who has been referred to an ERS. There were no negative aspects of the PPI activities undertaken in the study.

## Reflections

Being a resident of Plymouth, one PPI representative was able to attend all of the meetings held at the chief investigator's institution in person. Face-to-face contact with the PPI representative meant that a rapport was more readily generated than would have been possible if teleconferencing had been used.

The PPI representative on the TSC provided a welcome contribution to the various discussions on the problems faced with recruitment in the pilot phase of the trial. He took a keen interest in the wider issues faced by the trial team, such as ERS provision in the UK, national guidelines for PA and the choice of cut-off points for accelerometer-derived data that informed the primary outcome. The PPI representative provided a 'real-life' perspective on such matters, as he saw them.

## Participants

The study population was composed of patients who had been referred to an ERS administrator, or were about to be referred, mostly by a general practitioner (GP), and occasionally by a nurse to a local ERS for a programme of support to increase PA.

Patients were eligible for the study if they were aged between 16 and 74 years, inclusive, were contactable via e-mail, had some experience of using the internet and had one or more of the following conditions:

- obesity [i.e. a body mass index (BMI) of 30–40 kg/m<sup>2</sup>]
- a diagnosis of hypertension
- prediabetes
- type 2 diabetes
- lower limb osteoarthritis
- current or recent history of treatment for depression
- categorised as 'inactive' (i.e. 0 hours per week of physical exercise and in a sedentary occupation) or 'moderately inactive' (i.e. some activity but < 1 hour per week and in a sedentary occupation, or 0 hours per week of physical exercise and in a standing occupation) according to the General Practice Physical Activity Questionnaire (GPPAQ).<sup>36</sup>

Patients were excluded for the following reasons:

- They did not meet the eligibility criteria for their local ERS.
- They had an unstable, severe and enduring mental health problem.
- They were being treated for an alcohol or drug addiction that may have limited their involvement with the study.
- They were unable to use written materials in English, unless they had a designated family member or friend to act as translator.

## Intervention

All participants had been offered usual ERS. Participants allocated to the intervention group were additionally offered access to the e-coachER web-based support package. Development and delivery of the intervention is fully described in *Chapter 1, Developing the e-coachER intervention*.

## Usual care

There is currently no single model for ERSs in the UK, but the predominant mode of delivery involves referral to a programme (e.g. 10–12 weeks) of structured, supervised exercise at an exercise facility (e.g. gym or leisure centre) or a counselling approach to support patients to engage in a variety of types of PA.<sup>13</sup> ERSs operate diversely to accommodate patient choice and local availability of facilities, the common goal being to reduce the risk of long-term metabolic, musculoskeletal and mental health conditions as a result of physical inactivity. The three participating sites were selected from different regions of the UK (different ERS providers) to provide diversity of approach; the schemes are described in Ingram *et al.*<sup>1</sup>

## Recruitment procedures

Patients were identified as potentially eligible for the trial in a number of ways.

1. By health-care professionals in primary care at the point of being actively referred to an ERS or having been opportunistically found to be eligible for an ERS at a consultation with the primary care practitioner.
2. Via a search of patient databases at the participating GP practices (conducted by the local NIHR Primary Care Research Network team).
3. Via patient self-referral to the GP arising from community-based publicity for the trial.
4. By the ERS programme administrator on receipt of an ERS referral form from a GP practice.
5. By exercise advisors at the ERS service at enrolment on the ERS. With the patient's consent, the exercise advisor provided the local researcher with the patient's contact details for the purposes of the trial.

Potentially eligible patients were approached by the primary care practitioner or the local researcher, depending on how the patient had been identified. Some patients self-referred to the local researcher in response to publicity campaigns. These various means of identification and approach were designed to accommodate the variation in usual-care referral pathways to ERSs across the participating sites and individual GP practices.

Amenable patients were offered a study-specific participant information sheet (see *Report Supplementary Material 1*) by post, by e-mail or by hand (the route used largely depended on the preference of the participating GP practice or ERS service). Interested patients were asked to communicate their expression of interest to the local researcher via a prepaid reply slip, by telephone or by e-mail. On receipt of an expression of interest, the local researcher contacted the potential participant by telephone to discuss the trial, confirm eligibility and seek informed consent.

## Informed consent

Informed, written consent (see *Report Supplementary Material 2*) was obtained prior to undertaking the baseline assessment, either over the telephone or at a face-to-face visit, depending largely on the patient's preference but also on the availability of suitable venues, such as the GP practice. The original completed informed consent forms were held securely at the site and a copy was given to the participant.

In the case of telephone consent, the researcher was required to sign and date the informed consent form, but the participant was not required to sign or date their copy.

Patients who were deemed to be ineligible for inclusion in the study were informed of this outcome.

## Randomisation, concealment and blinding

On receipt of the baseline accelerometer at the Peninsula Clinical Trials Unit (PenCTU) (after 1 week of wear), participants were randomised to usual ERS or usual ERS plus access to e-coachER in a 1 : 1 ratio, stratified by site with minimisation by participant's perception of main medical referral reason (i.e. weight loss, diabetes control, reduce blood pressure, manage lower limb osteoarthritis symptoms, manage low mood/depression) and by self-reported IT literacy level on a visual analogue scale (i.e. lower or higher confidence).

To maintain concealment, the minimisation algorithm retained a stochastic element.

Randomisation was conducted by means of a secure, password-protected web-based system created and managed by the clinical trials unit (CTU).

Blinding of participants was not possible, given the nature of the intervention. Given that the primary outcome was an objective measure of PA recorded by accelerometer, and the secondary outcomes were assessed by a participant self-completed questionnaire, the risk of assessor bias was considered to be negligible in this study. However, to minimise any potential bias, the statistical analysis was kept blinded and the code for group allocation was not broken until the primary and secondary analyses had been completed. The ERS practitioners would not have been aware of trial participants' treatment allocations.

## Process evaluation: qualitative interviews

Participants who had engaged with the e-coachER website (i.e. logged on to the website, as a minimum) were invited to participate in one or more qualitative interviews to inform the process evaluation (see *Chapter 4, Qualitative process evaluation*).

## Data collection and management

Data were collected and stored in accordance with the Data Protection Act 1998<sup>37</sup>/General Data Protection Regulation 2016.<sup>38</sup>

## Participant numbering

Following receipt of an expression of interest, each patient was allocated a unique identification number and was then identified in all study-related documentation by this number and their initials. A record of names, addresses, telephone numbers and e-mail addresses linked to participants' identification numbers was stored securely on the study database at the CTU for administrative purposes only.

## Data collection

Data were recorded on study-specific paper-based case report forms (CRFs) by the local researcher, and participants completed a paper-based questionnaire booklet comprising validated and non-validated self-report outcome measures.

Accelerometers [GENEActiv™ Original accelerometer (version 3.0\_09.02.2015), Active Insights Kimbolton, UK; [www.geneactiv.org/](http://www.geneactiv.org/) (accessed 26 February 2020)] were configured for use prior to being issued to participants by the local researcher at baseline and the CTU thereafter, using GENEActiv software. A recording window of 10 days, starting at midnight of the day of issue and recording at 75 Hz, was pre-set, thus accounting for transits in the post while optimising the battery life of the device.

Accelerometers received by the CTU following 1 week of wear by the participant were physically cleaned with liquid detergent in accordance with the manufacturer's instructions before data were downloaded and linked to the participant identification number (see *Accelerometer data processing*). Accelerometers were then issued to other participants in the trial as required.

Data on participants' uptake of the ERS were collected via participant self-report at 4 weeks post baseline and 4 months post randomisation, and via the ERS service provider.

Recording and reporting of non-serious adverse events (AEs) in this study were not required. Serious adverse events (SAEs) were reported to the CTU via the self-report questionnaire booklet administered at 4 and 12 months, but were also reported to the CTU or local researcher by the participant (or relative) outside these time points, until the end of follow-up. SAEs were categorised using the Medical Dictionary for Regulatory Activities (MedDRA) Terminology Systems Organ Classification List Internationally Agreed Order Version 19.0, March 2016 ([www.meddra.org/sites/default/files/guidance/file/intguide\\_19\\_0\\_english.pdf](http://www.meddra.org/sites/default/files/guidance/file/intguide_19_0_english.pdf); accessed 26 February 2020).

All persons authorised to collect and record study data at each site were listed on the study site delegation logs, which were signed by the principal investigator.

## Data processing

### *Accelerometer data processing*

Accelerometer data were downloaded using the GENEActiv and analysed in software R (The R Foundation for Statistical Computing, Vienna, Austria) using package GGIR version 1.2–8 (<https://cran.r-project.org/web/packages/GGIR/index.html>).<sup>39</sup> GGIR performs autocalibration with the reference of local gravity.<sup>40</sup> Raw acceleration data are used to compute Euclidean norm minus one (ENMO in mg).<sup>41</sup> Data were analysed from the first to the final midnight using 5-second epochs. Participants were included in the main analysis if they achieved a minimum of 16 hours of wear-time for a minimum of 4 days (including at least 1 weekend day). Non-wear was detected if the standard deviation (SD) of two axes was < 13 mg with a range of < 50 mg in windows of 60 minutes. Time spent in activity intensities was established using published thresholds.<sup>42</sup>

Computed variables included average daily MVPA accumulated in any 5-second epochs. Ten-minute bouts of MVPA were detected when at least 80% of a 10-minute period was above the MVPA intensity threshold.<sup>43</sup> Total time accumulated in bouted and unbouted MVPA minutes was calculated by multiplying the average daily values by 7 to represent 1 full week.

Diurnal activity and nocturnal periods of inactivity were also estimated to determine if the intervention had an effect on reducing daytime inactivity and increasing sleep. Sleep duration was

established using sustained nocturnal inactivity bouts. An inactivity bout occurred when no change in arm angle  $> 5^\circ$  was observed for at least 5 minutes.<sup>44</sup> Diurnal inactivity represents the sustained inactivity bouts ( $> 5$  minutes) that occur in the day,<sup>43</sup> which includes naps, but omits other inactivity that results in measurable movement.<sup>45</sup> However, it is likely that some misclassification of this inactivity may occur.<sup>43</sup>

To explore if different ways of processing accelerometer data influenced the findings, four additional wear-time criteria were calculated:

1.  $\geq 16$  hours over any 4 days (irrespective of weekday/weekend day)
2.  $\geq 10$  hours for 4 days (including at least 1 weekend day)
3.  $\geq 10$  hours over any 4 days (irrespective of weekday/weekend day)
4. a minimum wear criterion of 1 day for 10 hours but with individuals weighted by the number of valid days with  $\geq 10$  hours of wear.

### **Case report forms and questionnaire booklets**

Original CRFs and questionnaire booklets were posted to the CTU, with copies of the CRF retained at the site. All data were double-entered by CTU staff into a password-protected Structured Query Language Server database and encrypted using Secure Sockets Layer (version V3, QuoVadis Global SSL ICA G3, QuoVadis Online Limited, Lincolnshire, UK). Double-entered data were compared for discrepancies using a stored procedure, and discrepant data were verified using the original CRF. Incomplete, incoherent, unreadable or other problem data in the CRF pages were queried with site staff by staff at the CTU during data entry to ensure a complete and valid data set. Self-reported data in the questionnaire booklet were not queried with participants.

The CTU staff completed further validation of data items and performed logical data checks after data collection had been completed. After all data-cleaning duties had been performed at the CTU, the final export of anonymous data was transferred to the statistician and health economist for analysis.

## **Baseline assessment**

Consented participants attended a baseline assessment with the local researcher. This assessment was conducted over the telephone or in person at a suitable venue in the community.

Demographic data were collected (i.e. age, gender, BMI, blood pressure, ethnic group, relationship status, domestic residence status, smoking status, employment status, education status, GPPAQ score, internet use capability, requirement for translator for trial purposes and clinical condition).

Information technology literacy level was determined using a visual analogue scale for self-reported 'confidence using the internet', where 1 = not at all confident and 10 = totally confident. Arbitrarily, scores of 1–5 were set to indicate a low literacy level and scores of 6–10 indicated a high literacy level, for the purposes of stratification.

'Clinical condition' was the participant's perception of the reason for referral to the ERS; where more than one medical condition was stated, the participant ranked these in order of importance and the most important reason was used as a stratification variable.

The participant was issued with the wrist-worn waterproof accelerometer to wear constantly for 1 whole week (day and night), and a self-report questionnaire booklet to complete at the beginning of the week-long period. At the face-to-face baseline assessments, the accelerometer was fitted by the local researcher; at telephone visits, the accelerometer (and self-report questionnaire booklet) were posted to participants. All participants were provided with a bespoke guidance sheet for wearing the



accelerometer (see *Report Supplementary Material 3*), including instructions to wear the accelerometer on the wrist of the non-dominant hand (i.e. the hand not favoured for writing). After 1 week of wear, participants were required to post the accelerometer and completed questionnaire to the CTU in a preaddressed padded envelope provided. A prepaid postal service was used so as not to incur costs to the participant.

The measures collected at baseline are summarised in *Table 2*.

## Follow-up assessments

The measures collected at follow-up are summarised in *Table 2*.

At 4 weeks post baseline, a short survey on initial uptake of the ERS was administered via e-mail.

**TABLE 2** Schedule of baseline and follow-up measures

Measure	Baseline	4 weeks post baseline	4 months post randomisation	12 months post randomisation	On completion of participants' ERS programme at site
Demographics	X				
Engagement with the ERS: self-reported		X	X		
Engagement with the ERS: ERS service provider's record					X
Accelerometer-recorded MVPA	X		X	X	
Self-reported MVPA	X		X	X	
Self-reported health and social care resource use	X		X	X	
Self-reported quality-of-life measure (EQ-5D-5L)	X		X	X	
Self-reported Hospital Anxiety and Depression Scale	X		X	X	
Self-reported process evaluation outcomes (confidence to be physically active; importance of being physically active; perceived frequency and availability of support; perceived autonomy over choices; involvement in self-monitoring and action-planning PA)	X		X	X	
Qualitative interviews as part of the process evaluation focusing on participants' experiences with the ERS and the intervention (optional for participants)		X			
Engagement with e-coachER (captured from the LifeGuide platform)		X			
EQ-5D-5L, EuroQol-5 Dimensions, five-level version.					

At 4 and 12 months post randomisation, participants were sent an accelerometer (along with the guidance sheet on how to wear it), a questionnaire booklet, and a pre-addressed, prepaid envelope to return the items to the CTU.

To maximise data completeness at follow-up assessments, participants were sent standard letters from the CTU: (1) 7 days before delivery of the accelerometer, (2) 3 days into the 10-day recording window as a prompt to begin wearing the accelerometer (if not already doing so) and (3) at 3 and 5 weeks after issue as a reminder to post the accelerometer to the CTU (for those participants who had not already done so). If a participant had not sent the accelerometer back to the CTU after 6 weeks, the local researcher telephoned the participant to remind them to return the device. Participants who returned the accelerometer to the CTU were provided with a £20 voucher for an online store as a token 'thank you' to maximise response rates.

Once a participant's involvement in the ERS had concluded, the ERS service providers completed a simple pro forma to confirm whether or not the participant attended an appointment with the exercise specialist and, if so, how many appointments were available to the participant.

## Measures

### *Primary outcome measure*

The primary outcome was the number of weekly minutes of MVPA, in  $\geq 10$ -minute bouts, measured objectively using the GENEActiv Original accelerometer,<sup>46</sup> over 1 week at 12 months post randomisation, compared with the control group. To be included, participants had to have provided activity recorded over 4 days, including a weekend day, for at least 16 hours per day.

### *Secondary outcome measures*

- Total weekly minutes of MVPA in  $\geq 10$ -minute bouts, measured objectively using an accelerometer, over 1 week at 4 months.
- Achievement of at least 150 minutes of MVPA, measured objectively by accelerometer, over 1 week at 4 and 12 months.
- Self-reported achievement of at least 150 minutes of MVPA over 1 week using the 7-day recall of PA<sup>47</sup> (7-day Physical Activity Recall questionnaire) at 4 and 12 months.
- Self-reported weekly minutes of MVPA at 4 and 12 months.
- Average daily hours of sedentary behaviour measured objectively using an accelerometer over 1 week at 4 and 12 months.
- Self-reported average daily hours of sleep over 1 week at 4 and 12 months.
- Self-reported health-related quality of life, assessed using the EuroQol-5 Dimensions, five-level version (EQ-5D-5L),<sup>48</sup> at 4 and 12 months.
- Self-reported symptoms of anxiety and depression, assessed using the Hospital Anxiety and Depression Scale (HADS),<sup>49</sup> at 4 and 12 months.
- Uptake of the ERS according to the attendance records held by the ERS service provider, with imputed participant-reported attendance at 4 weeks and/or 4 months where the ERS service data are missing.
- Adherence to PA using a composite measure to describe the proportion of participants in each arm of the trial who achieved at least 150 minutes of MVPA in bouts of at least 10 minutes at 4 months and were still doing so at 12 months.

### *Self-reported survey process measures*

The following survey items were adapted from existing measures or originally developed, using processes to be reported elsewhere in more detail, and were used as process measures:

- importance and confidence to be physically active (single items)
- perceived competence in being regularly physically active (four items)
- autonomous in decisions about PA (four items)
- availability of support (three items)
- frequency of support (three items)
- action-planning (five items)
- self-monitoring (two items).

The respective measures were not validated but exploratory analysis, to be reported in more detail elsewhere, indicated that Cronbach's alpha coefficients of all scales were  $\geq 0.77$ , using data from participants included in the primary analysis.

In the intervention group, we measured engagement with e-coachER. This included whether or not the participant visited the website at least once and whether or not they reached a stage of the online support to indicate that they have set and reviewed at least one PA goal [i.e. step 5 – users make their specific, measurable, achievable, relevant, time-bound (SMART) activity plan and then review their step goal and SMART activity goal].

### **Sample size**

In the absence of a published minimally important difference for MVPA, assuming a 'small' to 'moderate' standardised effect size of 0.35, we estimated that 413 participants were required, with 88% power and a two-sided alpha of 5%, assuming 20% attrition, or 90% power at a two-sided alpha of 5% allowing for 16% attrition [using 'sampsi' in Stata® version 14 (StataCorp LP, College Station, TX, USA)]. Given that the intervention was delivered at the level of the individual participant, clustering was not factored into the sample size calculation. Based on the baseline SD for MVPA total weekly minutes in  $\geq 10$ -minute bouts of 104–113,<sup>50</sup> an effect size of 0.35 corresponds to a between-group difference of 36–39 minutes of MVPA per week.

### **Statistical analysis**

Analyses were in accordance with International Conference on Harmonisation guideline 9 (ICH-9) statistical guidelines<sup>51</sup> for clinical trials and updated Consolidated Standards of Reporting Trials (CONSORT) reporting guidelines<sup>52,53</sup> for non-drug trials. All primary and secondary analyses were undertaken and reported in accordance with a prespecified detailed statistical analysis plan that was agreed with the Project Management Group, TSC and Data Monitoring Committee (DMC).

Following data lock by the CTU data manager, the statistician undertook primary analyses blinded to group (i.e. randomised groups were coded 'A' or 'B'). Following the blinded presentation of the primary results to the Project Management Group and agreed interpretation of the results, the groups were unblinded.

### *Descriptive analyses*

A summary of baseline characteristics and baseline outcome values in the intervention and control groups was undertaken and between-group equivalence was assessed descriptively. Because differences between randomised groups at baseline could have occurred by chance, no formal significance testing will be conducted.

### *Interim analysis*

No interim inferential analysis was planned and none was conducted.

### *Inferential analyses*

#### **Definition of comparison groups**

Intention to treat (ITT), complete case: groups according to original randomised allocation in participants with complete data (i.e. meeting required accelerometer wear-time) at 12-month follow-up.

Intention to treat, imputed: groups according to original randomised allocation in all participants.

Per protocol [complier-average casual effect (CACE)]: ITT complete-case participants who have completed step 5 – making your activity plans.

#### **Primary analysis**

The primary analysis using a linear model (continuous outcomes – using Stata ‘regress’) or logistic model (binary outcomes – using Stata ‘logistic’ command) compared primary and secondary outcomes between groups according to the principle of intention to treat (i.e. according to original randomised allocation) in participants with complete outcomes at 12 months. This adjusted for baseline outcome values and stratification (by site) and minimisation variables (participant’s perception of main medical reason for referral to the ERS and IT literacy level). Given that age and gender are known to be predictive of PA, these baseline characteristics were also added to the adjusted model.

Given the overdispersion and high frequency of the primary outcome, the primary mixed-effects model was found to be a poor fit. Therefore, alternative post hoc regression models were explored for the analysis of the primary outcome. These included a log-transformed mixed-effects model (with a constant added), a mixed-effect model (with outliers removed), negative binomial models and zero-inflated binomial models.

#### **Secondary analyses**

Secondary analyses were undertaken to compare groups at follow-up across all follow-up points, using a mixed-model repeated-measures approach (using Stata ‘xtmixed’ command). Secondary per-protocol analysis using a CACE approach (using Stata ‘ivregress’ command) was undertaken to examine the impact of adherence to the intervention on primary and secondary outcomes at 12 months post randomisation.

### *Subgroup analyses*

The primary analysis model was extended to fit interaction terms to explore possible subgroup differences in intervention effect in stratification and minimisation variables for the primary outcome at 12 months post randomisation. Given the relatively low power for testing interactions, these results were to be considered as exploratory only.

### *Sensitivity analysis to test the effects of different ways of processing accelerometer data*

Sensitivity analysis was undertaken using four additional wear-time criteria:

1.  $\geq 16$  hours over any 4 days (irrespective of weekday/weekend day)
2.  $\geq 10$  hours for 4 days (including at least 1 weekend day)
3.  $\geq 10$  hours over any 4 days (irrespective of weekday/weekend day)
4. a minimum wear criterion of 1 day for 10 hours but with individuals weighted by the number of valid days with  $\geq 10$  hours of wear.

### Handling of missing data

Missingness was defined as those participants with the absence of data at follow-up for one or more outcomes. Given that the proportion of patients with missing accelerometry data out of the total number of participants who fulfil the criteria of includable PA data ( $n = 243$ ) was small (i.e. 0–10 participants or  $< 5\%$ ), no imputation was undertaken for the primary outcome or any of the derived secondary outcomes. For EQ-5D-5L and HADS, missing data were replaced using multiple imputation using the covariates of age, gender, reason for referral and confidence in IT, and assuming that unobserved measurements were missing at random (using Stata 'mi' command). Using the same primary analysis model as described above, between-group outcomes were compared in ITT complete-case and imputed data sets for primary and secondary outcomes at 12 months post randomisation.

### Adverse events

Safety data and AEs were listed descriptively by group and include details of the event and the likely relatedness to either treatment.

### Data presentation

Results were reported as between-group mean differences with 95% confidence intervals (CIs); global  $p$ -values were provided with regard to categorical explanatory variables. The threshold for determining significant effects was  $p < 0.05$ . No adjustment of  $p$ -values was made to account for multiple testing, although the implications of multiple testing were considered when evaluating the results of the analyses.

### Model checking and validation

All analyses were undertaken using Stata version 14.2.

Stata coding for the primary analysis was prepared independently and the analyses were cross-checked.

Checks were undertaken to assess the robustness of models, including an assessment of model residual normality and heteroscedasticity.

## Changes to the project protocol

### Primary outcome measure and sample size

The original protocol featured an internal pilot. During the internal pilot phase, 180 participants were to be recruited over 3 months to provide sufficient information to justify progression to a main trial. Progression from the internal pilot to the main trial was dependent on recruitment rate and engagement with the intervention according to the scenarios in *Table 3*. In the main trial, an additional 1220 participants were to be recruited, giving a total of 1400 participants (recruited over 16 months).

**TABLE 3** Internal pilot to main trial progression rules

Criteria	Scenario 3	Scenario 2	Scenario 1
Percentage of internal pilot sample size target (180 participants) recruited (%)	$< 65$	65–79	$\geq 80$
Intervention engagement (% participants who access e-coachER at least once)	$< 65$	65–79	$\geq 80$
Proposed action	No progression	Discuss with TSC and funder about progression and resources needed to achieve target	Proceed to full trial

The recruitment rate during the internal pilot phase was lower than expected as a result of limitations on the time that primary care practitioners had available to approach potential participants, a delayed start at one of the research sites, poor uptake when patients were approached via a postal mailshot and a high ineligibility rate among patients who were identified via a primary care database.

In response to poor recruitment, the following strategies to increase recruitment were introduced in November 2015:

- The inclusion criterion for BMI was aligned with the ERS entry (upper BMI limit for the trial was originally 35 kg/m<sup>2</sup> and was raised to 40 kg/m<sup>2</sup>), and prediabetes was included as an inclusion criterion.
- Provision was made for the Birmingham and Plymouth sites to recruit participants via the ERS service (a strategy already in place at the Glasgow site), in addition to recruitment via primary care.
- Incentive payments to participants (for returning an accelerometer) were increased from a maximum of £40 per participant (£10 at baseline, £10 at 4 months and £20 at 12 months) to a maximum of £60 per participant (£20 at each of the aforementioned time points).

Having implemented these measures, the conditions for progression in terms of recruitment rate and engagement with the intervention were not met by the end of the internal pilot phase, despite a 4-month extension period. A 'recovery plan' was developed in collaboration with the funders, based on amending the choice of primary outcome.

The original primary outcome was achievement of at least 150 minutes of MVPA measured objectively by accelerometer over 1 week at 12 months. This outcome was based on the findings of a systematic review of ERSs<sup>14,54</sup> demonstrating that trials had primarily reported their outcomes according to percentage of participants reaching the NICE guidelines for PA level (i.e. 150 minutes of MVPA per week). We estimated that recruiting 700 participants per group would allow us to detect a difference at 12-month follow-up of at least 10% (intervention group 53% vs. control group 43%), assuming an attrition rate of 20% and small effect of clustering (intracluster correlation coefficient 0.006) at 90% power and 5% alpha. Thus, the original sample size was 1400 participants to be recruited over a 16-month period.

From the outset, the TSC and DMC had recommended that this dichotomous primary outcome measure be replaced with a continuous variable (i.e. total weekly minutes of MVPA). This was because:

- (a) A continuous primary outcome measure would be more relevant in this study population, in terms of detecting a small but clinically significant increase in minutes of MVPA.
- (b) Based on sample size calculations, this would offer greater statistical power than to the categorical assessment of whether or not participants reach a threshold of 150 minutes of MVPA. This would therefore afford a reduction in sample size.

The TSC and funders agreed to these changes (in August 2016) and the original sample size was reduced in accordance with this new primary outcome measure and revised sample size calculation, from 1400 to 413 participants (to be recruited over 21 months). A similar reduction in sample size was incorporated into the qualitative component of the process evaluation work.

The primary outcome was subsequently specifically defined as total weekly minutes of MVPA in  $\geq 10$ -minute bouts recorded objectively by accelerometer over 1 week at 12 months, in participants with activity recorded for at least 16 hours per day on at least 4 days, including 1 weekend day.

### ***Capture of exercise referral scheme attendance data***

Initially, uptake of the ERS was solely self-reported, captured via an e-mailed survey at approximately 4 weeks and a postal questionnaire at 4 months. Owing to poor compliance (especially at 4 weeks), data were sought from the ERS service providers, in addition to the self-reported data. Participants consented to the ERS service sharing their attendance data for the purposes of the trial.

### ***Omission of Short Form questionnaire-12 items data analysis***

Owing to an error in the compilation of the participant self-report questionnaire booklet, the Short Form questionnaire-12 items (SF-12) data collected could not be analysed in this study. We had intended to administer the SF-12 version 2 at each of the study time points but it transpired that a number of the response options for SF-12 version 1, instead of SF-12 version 2, had been printed in the questionnaire booklet in error.

## Chapter 3 Trial results: quantitative results

### Participant recruitment

A total of 450 participants were recruited (randomised) to the trial over a 20-month period (3 September 2016 to 10 April 2017).

Table 4 shows the number (%) of participants who entered the trial by referral source (i.e. by mailout from the GP or opportunistically in primary care, at the point of initial contact with the ERS providers, or by word of mouth or community advertisement) across the different sites.

### Flow of participants in the trial

Figure 4 shows the flow of participants through the trial. Of those expressing an interest in participating, 477 (63%) individuals were eligible. The main reasons for ineligibility were BMI being too high ( $n = 104$ , 14%), being too active according to the GPPAQ ( $n = 47$ , 6%) and clinical condition of interest not being present ( $n = 26$ , 3%). An additional 27 individuals (4%) could not be contacted following their expression of interest. A detailed CONSORT flow diagram is given in Appendix 2.

### Baseline comparability

The baseline characteristics of the whole sample ( $n = 450$ ) and those who were included in the primary analysis ( $n = 232$ ) are shown in Tables 5 and 6, respectively. The groups were well balanced.

### Study attrition

#### Loss to follow-up

A total of 450 participants were randomised. A total of 94 participants (21% of those randomised) were lost to follow-up: 47 (10%) participants declined to participate further and 47 (10%) participants were non-contactable (see Appendix 2).

There were no differences in age, BMI, gender, IT literacy and educational attainment between participants who were included in the primary analysis and those who were not.

TABLE 4 Route of participants into the study

Referral source	Site, n (%)			Total, n (%)
	Plymouth	Birmingham	Glasgow	
ERS	38 (25)	109 (71)	141 (100)	288 (64)
Primary care	102 (66)	45 (29)	0 (0)	147 (33)
Self-referral	15 (10)	0 (0)	0 (0)	15 (3)
Total	155 (100)	154 (100)	141 (100)	450 (100)



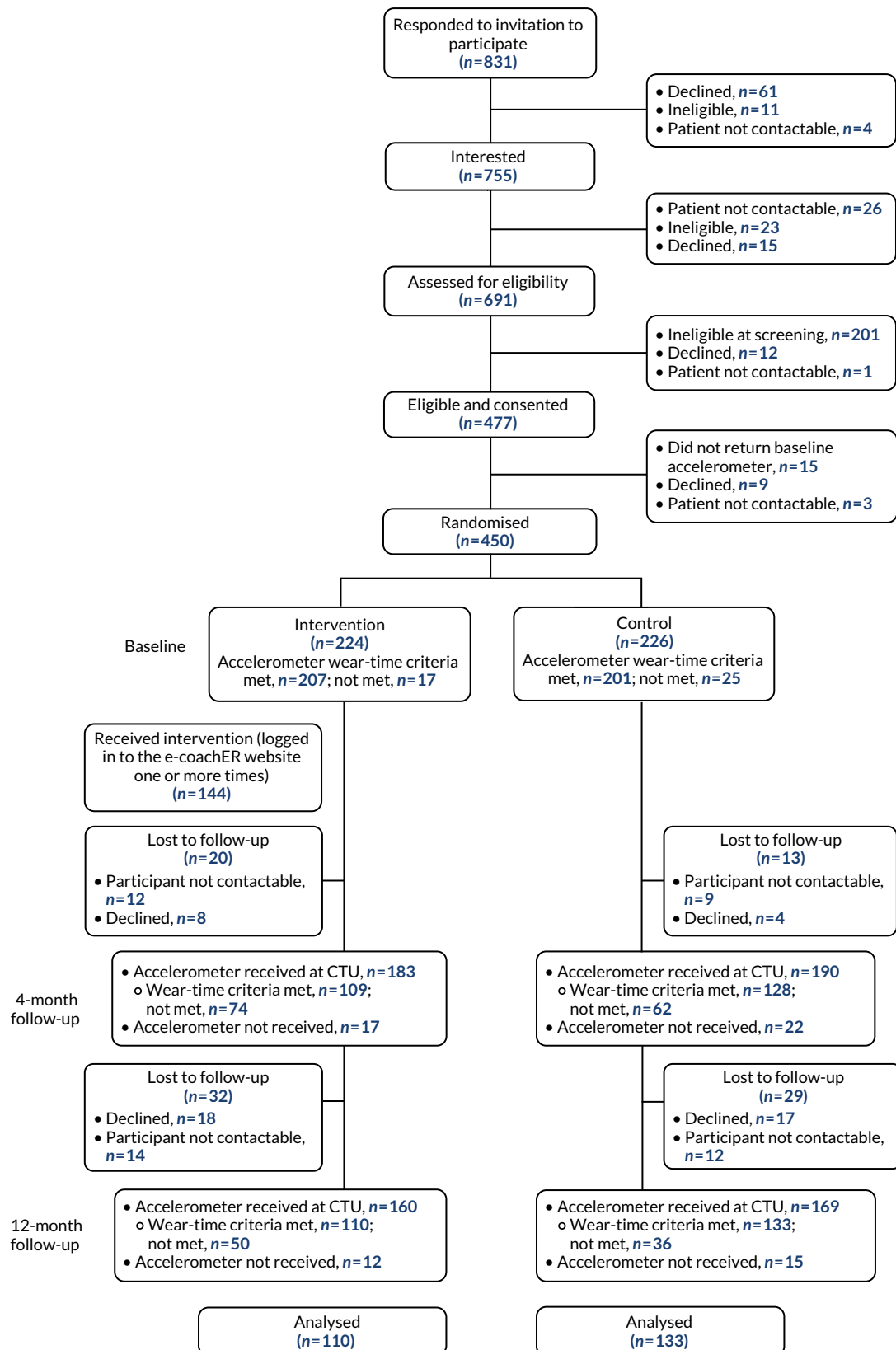


FIGURE 4 Participant flow.

TABLE 5 Baseline demographic and health-related characteristics of the sample

Variable	Control group	Intervention group	Both groups
N	226	224	450
Gender, n male (%)	84 (37)	76 (34)	160 (36)
Age (years), mean (SD) [range]	51 (14) [18–75]	50 (13) [20–73]	50 (12) [18–75]
BMI (kg/m <sup>2</sup> ), mean (SD) [range]	32.5 (4.4) [18.8–40.5]	32.7 (4.5) [18.8–40.4]	32.6 (4.4) [18.8–40.5]
Requirement for translator for trial purposes, n (%)	3 (1.3)	3 (1.3)	6 (1.3)
<b>GPPAQ score, n (%)</b>			
2 (inactive)	144 (63.7)	149 (66.5)	293 (65.1)
3 (moderately inactive)	82 (36.3)	75 (33.5)	157 (34.9)
<b>Participant's perception of any medical reason(s) for referral to ERS – prevalence, n (%)</b>			
Prediabetes	8 (4.0)	15 (7.7)	23 (5.8)
Type 2 diabetes	47 (20.8)	42 (18.8)	89 (19.8)
Osteoarthritis	64 (28.3)	45 (20.1)	109 (24.2)
Weight loss	182 (80.5)	182 (81.3)	364 (80.9)
Low mood	122 (54.0)	121 (54.0)	243 (54.0)
High blood pressure	79 (35.0)	68 (30.4)	147 (32.7)
<b>Ethnicity, n (%)</b>			
White	195 (86.3)	179 (79.9)	374 (83.1)
Black Caribbean	3 (1.3)	8 (3.6)	11 (2.4)
Black African	3 (1.3)	6 (2.7)	9 (2.0)
Black other	1 (0.4)	4 (1.8)	5 (1.1)
Indian	4 (1.8)	12 (5.4)	16 (3.6)
Pakistani	7 (3.1)	4 (1.8)	11 (2.4)
Bangladeshi	1 (0.4)	0 (0)	1 (0.2)
Chinese	0 (0)	0 (0)	0 (0)
Other	13 (5.8)	10 (4.5)	23 (5.1)
<b>Relationship status, n (%)</b>			
Single	78 (34.5)	78 (34.8)	156 (34.7)
Married	97 (42.9)	110 (49.1)	207 (46.0)
Civil partnership	5 (2.2)	2 (0.9)	7 (1.6)
Divorced or dissolved civil partnership	35 (15.5)	25 (11.2)	60 (13.3)
Widowed or surviving civil partnership	11 (4.9)	9 (4.0)	20 (4.4)
<b>Domestic residence status (live with), n (%)</b>			
Live alone	59 (26.1)	48 (21.4)	107 (23.8)
Partner	120 (53.1)	130 (58.0)	250 (55.6)
Parent	11 (4.9)	13 (5.8)	24 (5.3)
Child aged < 18 years	66 (29.2)	67 (29.9)	133 (29.6)

continued

TABLE 5 Baseline demographic and health-related characteristics of the sample (continued)

Variable	Control group	Intervention group	Both groups
Child aged $\geq 18$ years	39 (17.3)	53 (23.7)	92 (20.4)
Other family	10 (4.4)	8 (3.6)	18 (4.0)
Non-family	9 (4.0)	12 (5.4)	21 (4.7)
<b>Education status, n (%)</b>			
No qualifications	52 (23.0)	29 (12.9)	81 (18.0)
GCSEs	146 (64.6)	162 (72.3)	308 (68.4)
A level	71 (31.4)	96 (42.9)	167 (37.1)
First degree	36 (15.9)	54 (24.1)	90 (20.0)
Higher degree	22 (9.7)	20 (8.9)	42 (9.3)
Other	108 (47.8)	104 (46.4)	212 (47.1)
<b>Smoking status, n (%)</b>			
Smoker	34 (15.0)	32 (14.3)	66 (14.7)
Ex-smoker	90 (39.8)	89 (39.7)	179 (39.8)
Never smoked	102 (45.1)	103 (46.0)	205 (45.6)
<b>IT literacy level, n (%)</b>			
Low	36 (16)	35 (16)	72 (16)
High	190 (84)	189 (84)	379 (84)
<b>Site, n (%)</b>			
Birmingham	78 (34)	76 (34)	154 (34)
Glasgow	69 (31)	72 (32)	141 (31)
Plymouth	79 (35)	76 (34)	155 (35)
<b>Participant-reported main reason for referral, n (%)</b>			
High blood pressure	19 (8)	18 (8)	37 (8)
Low mood	42 (18)	42 (19)	84 (19)
Osteoarthritis	27 (12)	26 (12)	53 (12)
Type 2 diabetes and prediabetes	24 (11)	25 (12)	49 (11)
Weight loss	114 (50)	113 (50)	227 (50)
A level, Advanced level; GCSE, General Certificate of Secondary Education.			

TABLE 6 Baseline demographic and health-related characteristics of those included in the primary analysis

Variable	Control group	Intervention group	Both groups
N	124	108	232
Gender, n male (%)	44.0 (35.5)	36.0 (33.3)	80 (34.4)
Age (years), mean (SD) [range]	52.1 (13.4) [18.0–74.7]	49.9 (12.9) [20.6–72.9]	51.1 (13.2) [18.0–74.7]
BMI (kg/m <sup>2</sup> ), mean (SD) [range]	32.3 (4.3) [18.8–40.5]	32.6 (4.9) [18.8–40.4]	32.4 (4.6) [18.8–40.5]
Requirement for translator for trial purposes, n (%)	0 (0.0)	3 (2.8)	3 (1.3)

TABLE 6 Baseline demographic and health-related characteristics of those included in the primary analysis (*continued*)

Variable	Control group	Intervention group	Both groups
<b>GPPAQ score, n (%)</b>			
2 (inactive)	82 (66.1)	70 (64.8)	152 (65.5)
3 (moderately inactive)	42 (33.9)	38 (35.2)	80 (34.5)
<b>Participant's perception of any medical reason(s) for referral to ERS – prevalence, n (%)</b>			
Prediabetes	4 (3.7)	4 (4.3)	8 (4.0)
Type 2 diabetes	26 (21.0)	15 (13.9)	41 (17.7)
Osteoarthritis	40 (32.3)	22 (20.4)	62 (26.7)
Weight loss	100 (80.6)	84 (77.8)	184 (79.3)
Low mood	65 (52.4)	57 (52.8)	122 (52.6)
High blood pressure	47 (37.9)	38 (35.2)	85 (36.6)
<b>Ethnicity, n (%)</b>			
White	109 (87.9)	95 (88.0)	204 (87.9)
Black Caribbean	2 (1.6)	3 (2.8)	5 (2.2)
Black African	2 (1.6)	3 (2.8)	5 (2.2)
Black other	0 (0.0)	0 (0.0)	0 (0.0)
Indian	1 (0.8)	3 (2.8)	4 (1.7)
Pakistani	4 (3.2)	0 (0.0)	4 (1.7)
Bangladeshi	0 (0.0)	0 (0.0)	0 (0.0)
Chinese	0 (0.0)	0 (0.0)	0 (0.0)
Other	6 (4.8)	4 (3.7)	10 (4.3)
<b>Relationship status, n (%)</b>			
Single	40 (32.3)	37 (34.3)	77 (33.2)
Married	57 (46.0)	50 (46.3)	107 (46.1)
Civil partnership	3 (2.4)	2 (1.9)	5 (2.2)
Divorced or dissolved civil partnership	19 (15.3)	13 (12.0)	32 (13.8)
Widowed or surviving civil partnership	5 (4.0)	6 (5.6)	11 (4.7)
<b>Domestic residence status (live with), n (%)</b>			
Live alone	30 (24.2)	29 (26.9)	59 (25.4)
Partner	69 (55.6)	58 (53.7)	127 (54.7)
Parent	6 (4.8)	6 (5.6)	12 (5.2)
Child aged < 18 years	39 (31.5)	26 (24.1)	65 (28.0)
Child aged ≥ 18 years	19 (15.3)	25 (23.1)	44 (19.0)
Other family	4 (3.2)	3 (2.8)	7 (3.0)
Non-family	3 (2.4)	6 (5.6)	9 (3.9)

continued

TABLE 6 Baseline demographic and health-related characteristics of those included in the primary analysis (*continued*)

Variable	Control group	Intervention group	Both groups
<b>Education status, n (%)</b>			
No qualifications	29 (23.4)	11 (10.2)	40 (17.2)
GCSEs	84 (67.7)	83 (76.9)	167 (72.0)
A level	39 (31.5)	50 (46.3)	89 (38.4)
First degree	18 (14.5)	28 (25.9)	46 (19.8)
Higher degree	16 (12.9)	9 (8.3)	25 (10.8)
Other	59 (47.6)	49 (45.4)	108 (46.6)
<b>Smoking status, n (%)</b>			
Smoker	13 (10.5)	12 (11.1)	25 (10.8)
Ex-smoker	52 (41.9)	51 (47.2)	103 (44.4)
Never smoked	59 (47.6)	45 (41.7)	104 (44.8)
<b>IT literacy level, n (%)</b>			
Low	17 (13.7)	14 (13.0)	31 (13.4)
High	107 (86.3)	94 (87.0)	201 (86.6)
<b>Site, n (%)</b>			
Birmingham	43 (34.7)	34 (31.5)	77 (33.2)
Glasgow	29 (23.4)	34 (31.5)	63 (27.2)
Plymouth	52 (41.9)	40 (37.0)	92 (39.7)
<b>Participant-reported main reason for referral, n (%)</b>			
High blood pressure	10 (8.1)	10 (9.3)	20 (8.6)
Low mood	15 (12.1)	22 (20.4)	37 (15.9)
Osteoarthritis	18 (14.5)	13 (12.0)	31 (13.4)
Type 2 diabetes and prediabetes	14 (11.3)	10 (9.3)	24 (10.3)
Weight loss	67 (54.0)	53 (49.1)	120 (51.7)
A level, Advanced level; GCSE, General Certificate of Secondary Education.			

## Accelerometer and questionnaire booklet return rates

Accelerometer and questionnaire booklet return rates are given in *Table 7*. Receipt of the baseline accelerometer at the CTU was a prerequisite for randomisation; therefore, there is a 100% return rate for this accelerometer.

At 12 months, 329 participants returned the accelerometer (return rate of 92%). The wear-time criteria were met by 243 participants, this being 54% of those randomised (*Table 8*). At this time point, 325 participants returned the questionnaire booklet (return rate of 91%), that is 72% of those randomised.

In *Table 8*, purple shading denotes the number of participants meeting the wear-time criteria. A day was 'valid' when the accelerometer was worn for  $\geq 16$  hours on that day. Participants who did not meet the 'valid' criterion ( $n = 181$ ) were 94 participants lost to follow-up prior to the 12-month time point, 60 participants who returned an accelerometer at 12 months but failed to meet the wear-time criteria and 27 participants who remained in follow-up but did not return the accelerometer at 12 months.

TABLE 7 Accelerometer and questionnaire booklet return rates

Time point	Sent to participant (n)			Returned to CTU, n (% of sent)		
	Intervention	Control	Total	Intervention	Control	Total
<b>Accelerometer</b>						
Baseline	224	226	450	224 (100)	226 (100)	450 (100)
4 months	203	213	417	183 (90)	190 (89)	373 (89)
12 months	172	184	356	160 (93)	169 (92)	329 (92)
<b>Questionnaire</b>						
Baseline	224	226	450	220 (98)	220 (97)	440 (98)
4 months	204	213	417	166 (81)	183 (86)	349 (84)
12 months	172	184	356	155 (90)	170 (92)	325 (91)

TABLE 8 Accelerometer wear-time compliance at 12 months

Number of valid weekdays	Number of valid weekend days					Total
	0	1	2	3	4	
0	181					181
1	3	2	2			7
2	1		4			5
3	7	6	5			18
4	6	10	31			47
5	5	30	77	16	2	130
6		2	49	7		58
7			4			4
Total	203	50	172	23	2	450

Shading shows the participants meeting the wear-time criteria.

Losses to follow-up and non-compliance in returning the accelerometer were balanced across the two trial groups. Failure to meet the wear-time threshold was less consistent across the two trial groups.

## Intervention engagement

Table 9 shows the level of engagement in the various steps offered online.

The sample was evenly split, with 36% of participants not registering and logging in to e-coachER and 36% progressing through the support to record at least one goal review (i.e. having set a PA goal review, the participant logged back in about 1 week later to record PA against the goal and obtain feedback on the PA achieved against the goal set). Participants were routinely 'locked out' of accessing the web-based support to ensure that they did not complete it in one or two visits to the website, and then reminded by e-mail after 1 week to log in and continue with the steps and later record their PA in minutes, set goals and review them. Reaching step 5 involved > 4 weeks of intervention engagement.

TABLE 9 Intervention engagement

Stage started	Summary of content	Number (% of 224 in intervention group)
Did not register		81 (36)
Step 1	Quiz on benefits of PA	144 (64)
Step 2	Support to get active	133 (59)
Step 3	Encourage self-monitoring of steps	107 (48)
Step 4	Setting SMART step-count goals for next week	99 (44)
Step 5	Setting SMART goals for any PA for next week	96 (43)
Goal review	Review goal and personalised feedback	81 (36)
Step 6	Ways to achieve goals/overcoming barriers (optional)	N/A
Step 7	Overcoming setbacks (optional)	N/A
N/A, not applicable.		

Among all participants allocated to the intervention group, the mean number of goal reviews was 2.5 (SD 4.5), with a range of 0–52. Among the 144 participants who registered for e-coachER, they logged in for a mean and median number of times of 14.1 (SD 16.7) and 6, respectively, with a range of 1–101. Of these participants, 81 (36%) completed a goal review; the mean and median number of reviews was 14.4 (SD 13.8) and 4.5, respectively, with a range of 1–52.

Table 10 shows the mean, SD and median time spent during the respective stage (session) for the 144 participants who registered or 81 participants who completed at least one goal review. These data come with the limitation that participants may have left their browser open after some sessions rather than logging off, which leads to an overestimation of time spent. 'n' refers to the number of visits used to estimate the descriptive data for the time in sessions 1–5, the number of visits when a goal was first set and the number of sessions when a goal was reviewed.

On the basis that participants spent approximately 6 minutes logged in for steps (sessions) 1–5, and for 3 minutes for each goal review, for those 144 participants who registered, the total mean and median time that participants spent on steps 1–5 was 24.1 (SD 5.9) minutes and 30 minutes respectively.

For those 81 participants who completed at least one goal review, the overall mean and median time that participants spent doing goal reviews was 43.3 (SD 37.3) minutes and 21 minutes respectively. The 144 participants who registered spent a total mean and median time of 48.4 (SD 41.9) minutes and 36 minutes respectively. The range was 6–186 minutes.

TABLE 10 Descriptive data for time (minutes) spent engaging in the intervention

Status	Mean (minutes)	SD (minutes)	Median (minutes)	n
Visited steps 1–5 (from 144 participants who registered)	9.53	9.68	6.45	539
Goal-setting initial session (from 91 participants who set a goal)	7.81	7.54	5.92	91
Goal review session (from 81 participants doing $\geq 1$ goal review)	4.75	5.25	3.18	1034
Total	6.47	7.45	4.08	1664
n, number of visits used to estimate the descriptive data for the time in sessions 1–5, the number of visits when a goal was first set and the number of sessions when a goal was reviewed.				

## Descriptive data for the primary and secondary outcomes by group and time

The descriptive statistics for the primary and secondary outcomes at baseline and 4- and 12-month follow-up are shown in *Table 11* for all participants who provided data.

The groups were well balanced at baseline. Only 4% of participants achieved at least 150 minutes of accelerometer-recorded MVPA (in  $\geq 10$ -minute bouts) over 1 week at baseline and the average weekly minutes of MVPA (not in 10-minute bouts) was 49 minutes, which reflects our success in recruiting inactive or moderately inactive participants with chronic conditions. In contrast, 80% achieved 150 minutes of accelerometer-recorded MVPA without regard for  $\geq 10$ -minute bouts at baseline. Cassidy *et al.*<sup>55</sup> have also shown lower levels of accelerometer-recorded MVPA minutes when data are processed using  $\geq 10$ -minute bouts compared with bouts of at least 1 minute. This proportion drops to 36% for self-reported MVPA, reflecting the way that the 7-day Physical Activity Recall questionnaire (7-D PAR) measure focuses on only discrete bouts of memorable MVPA. There were also no baseline differences between groups for the EQ-5D-5L and the two HADS scales.

Descriptive data for PA and participant-reported outcomes are also shown in *Table 11* for those providing data at baseline, 4 and 12 months by trial arm, without controlling for baseline or other covariates.

**TABLE 11** Summary descriptive data for primary and secondary outcomes at baseline and 4- and 12-month follow-up

Variable	Baseline		4-month follow-up		12-month follow-up	
	Control group	Intervention group	Control group	Intervention group	Control group	Intervention group
<b>Primary outcome</b>						
Total weekly minutes of MVPA in $\geq 10$ -minute bouts, <sup>a</sup> n (mean); SD	201 (30.2); 105.8	207 (31.8); 53.7	128 (30.9); 64.5	109 (38.4); 74.5	133 (18.7); 37.6	110 (35.4); 78.3
<b>Secondary outcomes</b>						
Average daily minutes of MVPA, <sup>a</sup> n (mean); SD	201 (45.6); 35.6	207 (53.1); 35.9	128 (46.3); 37.8	109 (58.3); 35.9	133 (42.6); 30.1	110 (51.9); 36.6
Weekly achievement of at least 150 minutes of MVPA in $\geq 10$ -minute bouts, <sup>a</sup> n/N (%)	8/201 (4)	9/207 (4)	2/128 (2)	7/109 (6)	3/133 (2)	6/110 (5)
Weekly achievement of at least 150 minutes of MVPA, <sup>a</sup> n/N (%)	149/201 (74)	178/207 (86)	98/128 (76)	99/109 (91)	99/133 (74)	93/110 (85)
Weekly achievement of at least 150 minutes of MVPA self-reported, n/N (%)	83/220 (37)	77/220 (48)	94/183 (51)	88/166 (53)	76/170 (45)	76/154 (49)
Average daily diurnal inactivity (hours), <sup>a</sup> n (mean); SD	199 (1.7); 1.1	205 (1.5); 1.1	125 (1.4); 1.1	109 (1.4); 0.9	99 (1.4); 1.0	78 (1.5); 1.0
Average daily sleep (hours), <sup>a</sup> n (mean); SD	199 (6.8); 1.5	205 (6.9); 1.2	125 (6.7); 1.3	109 (6.7); 1.4	128 (6.8); 1.5	110 (7.0); 1.5
EQ-5D-5L (Devlin values), n (mean); SD	216 (0.74); 0.24	215 (0.76); 0.23	162 (0.72); 0.26	148 (0.76); 0.25	158 (0.72); 0.26	138 (0.73); 0.27
HADS-D, n (mean); SD	217 (7.6); 4.5	214 (7.4); 4.7	164 (7.4); 4.8	147 (6.0); 4.7	156 (7.1); 4.8	139 (6.3); 5.1
HADS-A, n (mean); SD	217 (8.7); 4.6	214 (8.6); 5.1	164 (8.5); 4.8	146 (7.5); 5.0	156 (8.4); 4.8	139 (7.6); 5.2

HADS-A, HADS anxiety score; HADS-D, HADS depression score.

<sup>a</sup> Fulfil the criteria of includable PA data.



Qualitatively, the intervention group was more active than the control group at 4 and 12 months for all primary and secondary outcomes. The intervention group also qualitatively had higher well-being (EQ-5D-5L) and lower depression and anxiety scores than the control group at 4 and 12 months.

## Primary outcomes

The primary outcome, ITT complete-case analysis showed a weak indicative effect in favour of the intervention group in the primary outcome at 12 months (mean difference 11.8 weekly minutes of MVPA, 95% CI -2.1 to 26.0 minutes;  $p = 0.10$ ) (Table 12). A plot of the repeated-measures model estimates for the primary outcome over time for the intervention and control groups is shown in Appendix 3. Although the alternative model  $p$ -values varied somewhat, a similar pattern of results was seen across alternative post hoc models. In interpreting these results, it is important to recognise the limitations of all these models: lack of fit of the predefined primary and post hoc models, and the need to assume data as counts with both negative binomial and zero-inflated binomial models.

The results of the CACE analysis for the primary outcome were consistent with the ITT results (Table 13). In other words, when controlling for whether or not intervention participants completed a prespecified 'dose' of the intervention [i.e. they completed a goal review (reached step 5)], this made no difference to the findings, but qualitatively the difference between the intervention and control groups did appear to be larger (in favour of the intervention).

TABLE 12 Comparison of intervention and control groups: primary analyses

	Primary analysis	Secondary analysis	
Primary outcome	ITT complete-case comparison at 12 months, <i>n</i> , coefficient <sup>a</sup> (95% CI); <i>p</i> -value	ITT imputed comparison at 12 months	Complete-case comparison at all follow-up points, <i>p</i> -value for interaction between intervention effect and time
Total weekly minutes of MVPA in ≥ 10-minute bouts	232, 11.8 (−2.1 to 26.0); 0.10 <sup>b</sup>	Not calculated	0.63
	223, 2.5 (−5.8 to 10.7); 0.55 <sup>c</sup>		
	232, 1.2 (0.8 to 1.5); 0.27 <sup>d</sup>		
	232, RR 1.90 (0.90 to 4.00); 0.09 <sup>e</sup>		
	232, RR 1.59 (1.13 to 2.25); 0.01 <sup>f</sup>		
RR, rate ratio.			
a Mean difference in weekly minutes unless otherwise stated.			
b Primary analysis mixed-effects model (mean difference).			
c Post hoc model 1 with outliers (> 200) dropped (mean difference).			
d Post hoc model 2 log with a constant of 5 added (exponentiated mean difference).			
e Post hoc model 3 negative binomial model (RR).			
f Post hoc model 4 zero-inflated negative binomial model (RR).			
Models adjusted for stratification variables age, gender, baseline scores and random effects for site, and fulfil the criteria of includable PA data.			

TABLE 13 Complier-average casual effect analysis of the primary outcome at 12 months

Variable	Between-group difference, $n$ , mean difference (weekly minutes) (95% CI); $p$ -value
Total weekly minutes of MVPA in $\geq 10$ -minute bouts	232, 22.9 (-3.4 to 47.8); 0.09
Model adjusted for stratification variables age, gender, baseline scores and random effects for site, and fulfil the criteria of includable PA data.	

As Table 14 shows, there was no evidence of any interactions between stratification variables and age and gender with the intervention effect for the primary outcome at 12 months. The ITT complete-case model was adjusted for stratification variables age, gender and baseline scores, and random effects for site and fulfil the criteria of includable PA data.

Table 15 shows the descriptive data for participants included in the primary analysis ( $n = 232$ ). Data shown for the 4-month assessment are from participants who were included in the primary analysis and also had complete data at 4 months. The intervention group had qualitatively greater mean weekly minutes of MVPA than the control group at baseline.

An analysis of complete data available at both baseline and 4 months (Table 16) shows that the control group significantly increased MVPA up to 4 months, whereas the intervention group did not. Between baseline and 12 months, there were no changes in either group, although qualitatively the control group had reduced their MVPA.

TABLE 14 Subgroup analyses of the primary outcome at 12 months

Variable	Interaction <i>p</i> -value	Subgroup coefficient (95% CI)
Age	0.10	-0.9 (-1.2 to 0.2) <sup>a</sup>
Gender	0.91	
Male		16.7 (-5.2 to 38.7)
Female		10.3 (-7.8 to 17.9)
Trial site	0.20	
Plymouth		4.3 (-15.2 to 23.9)
Birmingham		19.4 (-9.8 to 48.8)
Glasgow		9.0 (-9.8 to 27.8)
Participant's perception of main medical referral reason	0.33	
Control diabetes		11.9 (-0.1 to 24.1)
Weight loss		7.3 (-9.5 to 24.2)
Lower blood pressure		20.6 (-5.9 to 27.2)
Manage lower limb osteoarthritis symptoms		21.1 (-8.1 to 32.2)
Manage mood/depression		25.1 (-32.4 to 82.7)
IT literacy level	0.59	
Lower confidence		2.3 (-6.4 to 11.0)
Higher confidence		13.5 (-2.2 to 29.2)

<sup>a</sup> Per year of age increase.

TABLE 15 Accelerometer-recorded mean weekly MVPA minutes (in  $\geq 10$ -minute bouts) among participants with complete data at baseline and at 4 and 12 months

Variable	Baseline		4 months		12 months	
	Control group	Intervention group	Control group	Intervention group	Control group	Intervention group
MVPA minutes (in $\geq 10$ -minute bouts), <i>n</i> , mean (SD)	124, 22.6 (60.0)	108, 33.5 (53.8)	95, 31.7 (67.3)	77, 41.8 (82.4)	124, 17.6 (35.4)	108, 36.1 (78.9)

Data from participants included as per primary analysis with 232 participants providing data at baseline and 12 months and, of these, from the 172 who provided data at 4 months.

**TABLE 16** Changes in mean weekly MVPA minutes (recorded in  $\geq 10$ -minute bouts) in both trial groups from baseline to follow-up assessments

Variable	Mean difference, n, mean (SD) [95% CI]; p-value	
	Control group	Intervention group
Baseline vs. month 4	118, 8.2 (32.1) [2.4 to 14.1]; 0.006	105, 6.4 (68.1) [-6.7 to 19.6]; 0.334
Baseline vs. month 12	124, -5.0 (52.2) [-14.3 to 4.3]; 0.288	108, 2.6 (74.5) [-11.6 to 16.8]; 0.721

## Secondary outcomes

Results of the complete-case imputed ITT and repeated-measures analyses (including both 4- and 12-month follow-ups) for the PA secondary outcomes appeared consistent with the analysis for the primary outcome (see Table 12). As Table 17 shows, there were no significant between-group differences in ITT complete-case analyses for any of the secondary outcomes at 12 months.

**TABLE 17** Comparison of intervention and control groups: secondary outcome analyses

Variable	Primary analysis	Secondary analysis	
	ITT complete-case comparison at 12 months, n, coefficient <sup>a</sup> (95% CI); p-value	ITT imputed comparison at 12 months, n, coefficient <sup>a</sup> (95% CI); p-value	Complete-case comparison at all follow-up points, p-value (for interaction between intervention effect and time)
Average daily minutes of accelerometer-recorded MVPA	232, 1.9 (-3.8 to 7.7); 0.51	Not calculated	0.68
Weekly achievement of $\geq 150$ minutes of accelerometer-recorded MVPA in $\geq 10$ -minute bouts	232, OR 3.80 (0.16 to 20.92); 0.12	Not calculated	0.03
Weekly achievement of $\geq 150$ minutes of accelerometer-recorded MVPA	232, OR 1.67 (0.82 to 3.42); 0.16	Not calculated	0.23
Weekly achievement of $\geq 150$ minutes of self-reported MVPA	324, OR 1.23 (0.79 to 1.90); 0.36	450, OR 1.55 (0.99 to 2.42); 0.05	0.39
Average daily diurnal inactivity	226, 0.6 (0.5 to 0.7); < 0.0001	Not calculated	0.66
Average daily sleep	226, 0.3 (-0.1 to 0.6); 0.11	Not calculated	0.18
ERS attendance	446, OR 1.13 (0.72 to 1.79); 0.58	450, OR 1.09 (0.70 to 1.71); 0.70	-
EQ-5D-5L Devlin measure	290, 0.00 (-0.4 to 0.05); 0.89	450, 0.01 (-0.03 to 0.04); 0.70	0.99
HADS-D	289, -0.2 (-1.0 to 0.6); 0.44	450, -0.2 (-0.9 to 0.6); 0.63	0.02
HADS-A	289, -0.5 (-1.2 to 0.2); 0.20	450, -0.2 (-1.0 to 0.5); 0.52	0.05

OR, odds ratio.

<sup>a</sup> The coefficient is mean difference unless otherwise stated.

Models adjusted for stratification variables age, gender, baseline scores and random effects for site, and fulfil the criteria of includable PA data.

The ITT imputed comparison at 12 months showed that the intervention group had a greater proportion of participants achieving  $\geq 150$  minutes of self-reported MVPA ( $p = 0.05$ ) than the control group. In the repeated-measures analyses (including both 4- and 12-month follow-ups), a greater proportion of intervention participants achieved  $\geq 150$  minutes of accelerometer-recorded MVPA (in  $\geq 10$ -minute bouts) than control group participants. As *Table 11* shows, 2% and 6% of the participants achieved this at 4 months in the control and intervention groups, respectively, and 2% and 5% at 12 months, respectively.

There were no significant between-group differences in the ITT complete-case or imputed comparison analyses for EQ-5D-5L scores or for the HADS anxiety and depression scores at 12 months. In complete-case repeated-measures analyses (including both 4- and 12-month follow-ups), the intervention participants reported lower depression ( $p < 0.05$ ) and anxiety ( $p = 0.05$ ) scores than the control group.

Exercise referral scheme uptake was derived from records held by the ERS service provider, with imputed participant-reported attendance at 4 weeks and/or 4 months where the ERS service data were missing. Data were not available via any of the three sources for four participants (control group,  $n = 3$ ; intervention group,  $n = 1$ ), resulting in 223 participants in each group with ERS uptake data. A total of 173 participants (78%) in the control group attended the ERS at least once, compared with 167 participants (75%) in the intervention group.

## Adverse events

In total, 42 SAEs were reported among 35 participants (see *Appendix 4*), which were all deemed to be either 'not related' or 'unlikely to be related' to the trial. In the control group there were 26 SAEs among 21 participants and in the intervention group there were 16 SAEs among 14 participants. One SAE was reported as a life-threatening event (asthma attack) and all other SAEs were hospitalisations. SAEs were consistent with the patient population.



## Chapter 4 Mixed-methods process evaluation

This chapter presents the findings from both qualitative and quantitative methods and brings the two together to help understand and explain the findings from the main analyses presented in *Chapter 3*.

### Introduction

The overarching aim of the e-coachER trial was to determine whether or not adding support to usual ERS would be more clinically effective and cost-effective than usual ERS alone for supporting increases in PA in inactive patients referred to an ERS with a range of chronic conditions. The qualitative part of this chapter will explore participants' and e-coachER researchers' views and experiences of the support package and how it did or did not contribute to changes in PA. The quantitative part of the chapter will seek to understand if specific survey process measures were changed by the intervention, compared with usual ERS, as predicted from our logic model (*Figure 5*). Finally, we explore whether or not changes in the process outcomes mediated intervention effects on the primary outcome.

Previous research has quantitatively and qualitatively explored the barriers to and facilitators<sup>19,56</sup> of engaging in ERS, and the moderators of ERS engagement.<sup>15,57,58</sup> The e-coachER intervention was designed to help overcome many of the reported barriers to, and enhance the use of facilitators of, attending ERSs, becoming physically active in other ways, or both, through this primary care-based intervention.<sup>59</sup>

The e-coachER intervention is theoretically underpinned by self-determination theory,<sup>31</sup> which asserts that all humans possess three innate basic psychological needs (i.e. autonomy, competence and relatedness). When met, these needs foster intrinsic motivation resulting in personal growth and satisfaction. A range of behaviour change techniques<sup>35</sup> based on self-determination theory were employed within e-coachER's seven 'steps to health' (see *Table 1*), so this process evaluation seeks to establish whether or not the intervention influenced basic psychological needs and behaviour change processes.

A mixed-methods process evaluation seeks to best understand how participants engaged in the intervention (and trial methods) and what the consequences were with respect to our logic model.

### Qualitative process evaluation

The logic model shown in *Figure 1* has been adapted to show the causal pathways proposed to contribute to behaviour change and intervention outcomes and the objectives for the qualitative work (see *Figure 5*).

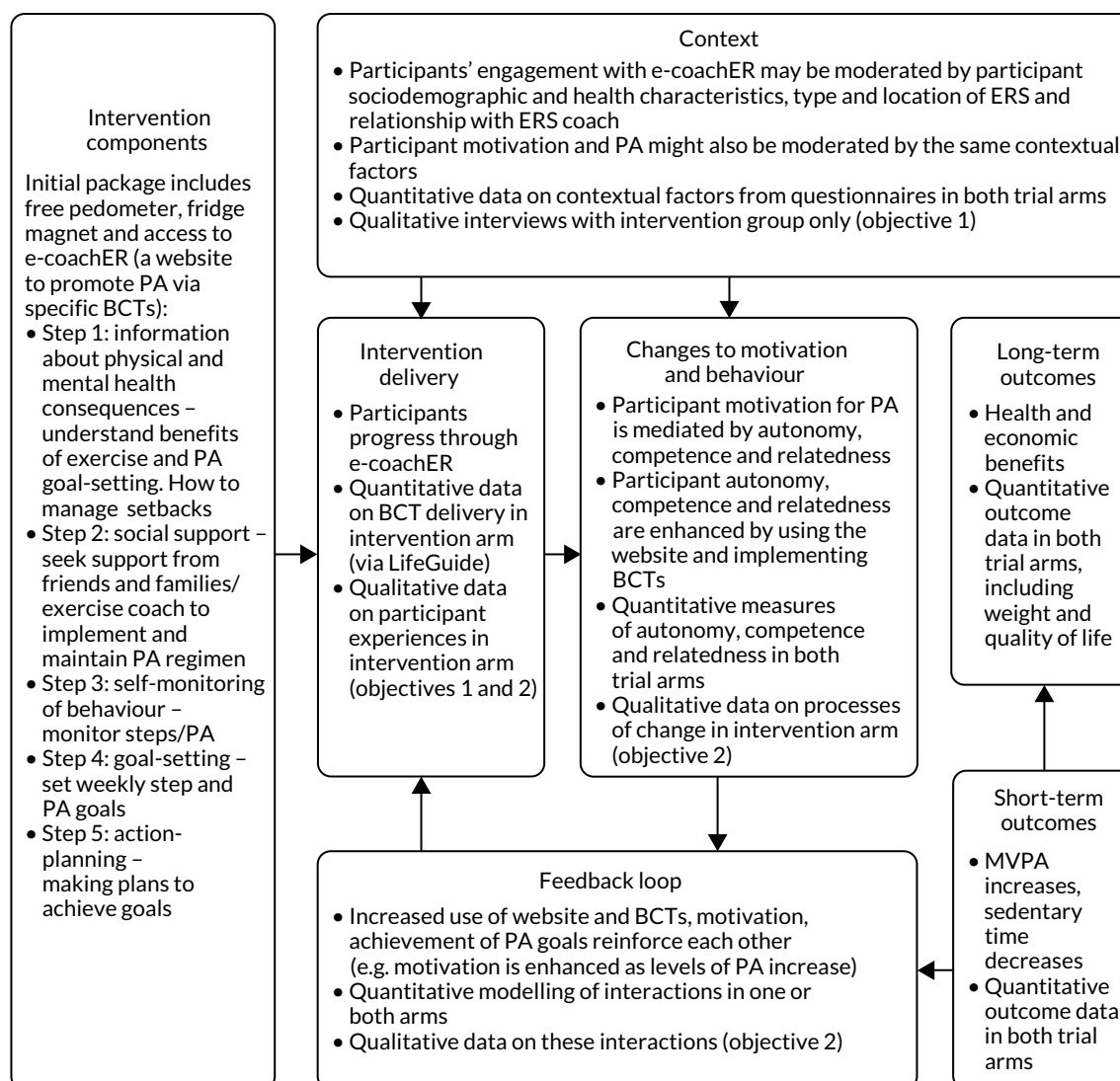
#### Aims and objectives

The qualitative interviews primarily aimed to explore how participants experienced and engaged with the e-coachER intervention.

The objectives were to explore:

1. whether the impact of the intervention is moderated by medical condition, age, gender, socioeconomic status, IT literacy or ERS characteristics
2. the mechanisms through which the intervention may have an impact on the outcomes.

The implementation and delivery of the trial and recommendations for future research in this area were also explored with participants and with the trial research assistants, who provided their views on e-coachER and their role in the study.



**FIGURE 5** The e-coachER logic model, adapted to show relationship with qualitative research objectives. Reproduced with permission from Ingram *et al.*<sup>1</sup> This is an Open Access article distributed in accordance with the terms of the Creative Commons Attribution (CC BY 4.0) license, which permits others to distribute, remix, adapt and build upon this work, for commercial use, provided the original work is properly cited. See: <http://creativecommons.org/licenses/by/4.0/>. The figure includes minor additions and formatting changes to the original.

## Methods

### Recruitment

Semistructured interviews were originally planned with a purposeful sampling framework (considering gender, age, underlying health condition and trial site). The trial sample size was subsequently reduced with a corresponding reduction in the number of interview participants and a change to focus the sampling from across the three sites. All participants who had logged on to the website (at least once) were approached by the CTU team to take part in a qualitative interview. Those expressing an interest were then telephoned or e-mailed by the researcher (NC or RT), who explained the interview purpose and process. Participants were invited to take part in an initial interview and to give permission to be contacted for follow-up telephone interviews (up to three were planned) over the course of the intervention period. Participants provided informed consent to participate in the qualitative interview (in addition to prior consent to take part in the RCT). As most interviews were carried out by telephone,

the informed consent form for the qualitative interview component was read point by point to the participant and signed by the researcher. Interviews were recorded, transcribed verbatim and anonymised.

Interviews with researchers at each research site were carried out following the completion of recruitment.

## Interviews

### Interviews with participants

Interviews were conducted at different stages of participation in the trial as it was anticipated that not everyone allocated to the intervention would progress through all of the steps to health. Each individual was invited to participate in an interview and further follow-up interviews, which enabled interviews to be conducted over the whole duration of the e-coachER intervention period (with online support available for up to 12 months).

The interview topic guide for participants (see *Appendix 5*) focused on each of the steps to health. Participants were also asked for their views on the welcome pack, the overall online support and the pedometer. Participants were asked to identify if and how they thought e-coachER provided support for ERSs, and for maintaining PA over and above attending their ERS. Participants were also asked to put forward any suggestions to improve or modify e-coachER.

The topic guide was also designed to gauge the participant's development of self-regulatory skills (e.g. self-monitoring, goal-setting) and the extent to which the intervention enhanced a sense of autonomy (control), competence and relatedness. However, these terms were not used explicitly; instead, the researchers used their knowledge of the guiding principles of the e-coachER intervention to prompt the participant to expand on their responses to the broader topic guide questions.

### Interviews with research assistants

The interview topic guide (see *Appendix 5*) focused on exploring issues surrounding the delivery of the trial, including recruitment and an exploration of processes that worked well, and what and where improvements could be made.

## Analysis procedure

Interviews were audio-recorded, transcribed verbatim and anonymised, with any personal data or ways of identifying participants removed. Transcripts were imported into NVivo 11 (QSR International, Warrington, UK) for data management and coded by one researcher (Rohini Terry) following an initial period of coding by Nigel Charles. A thematic analysis was performed to identify key findings, initially focusing on 'top-level' themes reflected in the logic model (see *Figure 5*). Additional in-depth analysis took place to further explore the data. Rohini Terry, Jeffery Lambert and Sarah Dean discussed the emerging codes and themes, and a consensus about these was reached. More in-depth analysis was also undertaken, and this will be fully reported in a forthcoming manuscript as the main publication arising from the qualitative research. Results are reported to (1) address the objectives and (2) give the findings emergent from the data.

## Results

### Participant sample and interviews

Of the 144 participants approached for interview, 36 participants (25%) expressed an initial interest in taking part. Thereafter, six participants who had initially expressed an interest did not respond to the invitation for interview. It was not possible to make contact with a further three participants. Hence, 27 participants (18%) who had logged on to e-coachER at least once were recruited to take part in the qualitative interview. Nineteen participants completed a single interview. Seven participants completed more than one interview several weeks apart, with one participant completing four interviews, three participants completing three interviews and three participants completing two interviews. Therefore, 38 interviews were carried out in total, each lasting between 16 and 80 minutes; the average interview



length was approximately 48 minutes. In total, 11 participants from Plymouth, nine participants from Birmingham and six participants from Glasgow took part in a qualitative interview. Participants had logged on to e-coachER at least once. The majority had progressed to the point that they were automatically locked out of the website for the first time (i.e. prior to step 2). At the time of the initial interview being conducted, participants may not have engaged with or progressed through all of the steps to health. Interviewing at these points, and as participants progressed through the steps, was intentional as it was important to obtain the experiences of those who did not progress as well as those who did. Interviews were also conducted with three research assistants, one from each site.

Table 18 provides a summary of interviewed participant demographics: gender, health condition, age, confidence using internet/IT, geographical location and access to IT facilities.

### Exploring the extent to which the impact of the intervention is moderated by medical condition, age, gender, socioeconomic status, information technology literacy or exercise referral scheme characteristics

A number of factors were identified as possibly affecting participant engagement with e-coachER and/or the impact of the intervention. These reasons included ill health, issues related to time and other issues specific to the individuals' circumstances.

In some cases, illness and comorbidities (e.g. stroke) made it harder for participants to fully engage with e-coachER:

*I have put some goals in there, erm, but as I think I hope you are aware, erm, I had a stroke a while ago, about 10 weeks ago, erm, so I'm being a bit slow, a bit cautious at the moment and I'm not going to, I can't think of the word, erm, I'm not making my goals too high.*

P09

TABLE 18 Characteristics of participants (n = 26) involved in interviews

Characteristic	Category	
Gender (n)	Female	20
	Male	6
Health condition (n)	Weight loss only	5
	Weight loss plus other morbidities but not low mood	4
	Weight loss and low mood only	7
	Low mood only	2
	Low mood and other morbidity but not weight loss	1
	Weight loss plus low mood and other morbidities	5
	No low mood, not weight loss, other physiological conditions	2
Age range (years)	Female	28–69
	Male	39–72
Confidence using internet/IT (n)	Low	0
	High	26
Participants at each research site (n)	Plymouth	11
	Birmingham	9
	Glasgow	6
Access to IT facilities (n)	Home/work access/mobile	22
	Mobile not home access	3
	Public only, not mobile access	1

For some participants, other unexpected life events made it difficult to engage with or experience benefits from e-coachER:

*Yeah I mean, again, I had the motivation to do it it's just I've had things going on that have forced my hand into stopping. But now I have, I do genuinely have the intention to restart and keep it up definitely ... I have an illness and a loss in the family ... It's stopped everything in all honesty ... Everything in my life ... Has been ground to a halt virtually.*

P08

By contrast, other participants found that, if their health condition had a negative impact on their motivation or ability to exercise, e-coachER provided reassurance and fostered their sense of competence:

*In a way that's saying look you haven't achieved everything that you said you were going to that's fine, but there are reasons for it and do you know what, that's OK. If you're too sore that you couldn't do it. If you're ill you couldn't do it. You know if you were in a particularly low mood that day like if you're in a low mood 'here's a little bit of information for you' and that little bit of information on the low mood, I suffer from depression so the low mood one is really part of it.*

P05

Access to IT facilities was generally good, and participants had high levels of confidence using the internet. A number of participants reported IT-related difficulties that may have an impact on e-coachER engagement and use and some felt that other apps or similar support provided more in terms of functionality:

*I didn't feel it was that user friendly especially 'cos I had used, sort of, [a commercially available app] and things like that in the past. And as I was comparing the two, sort of, the design of it I didn't find e-coachER that great just the white and the green. I also was using the [a commercially available app] and I found that one a lot better because I was able to keep track of exactly what I was doing in a lot more of an easier way than that.*

P22

## Exploring the mechanisms through which the intervention may have an impact on the outcomes

Most participants found that e-coachER was an easy-to-understand, flexible and supportive resource:

*... it's [the e-coachER website] given me support as well and there's always, as I say, sometimes there's information there to look at. ... it's changed my attitude to exercising because, as I say, I was not very eager to do it but now I've done it and I'm enjoying it and I have enjoyed it from the start because it's just I've seen the results basically and that's really given me a boost.*

P02

Most reported the package, or aspects of it, to be of some utility, for example acting as a prompt to increase PA:

*I suppose really it is a reminder to actually do it.*

P13

The e-coachER intervention was also described as providing an 'incentive' (P02), 'a bit of a lift' (P09) or a 'pat on the back' (P11) and that simply having access to e-coachER was motivating:

*My initial issue was the motivation and confidence that were missing to go and get started, which e-coachER has been very instrumental in and then once I was started now I've got that and I've got the benchmark of doing this.*

P16

The goal-setting aspects of the e-coachER support package, particularly in conjunction with the pedometer and setting step-count goals, using either the e-coachER website or the tear-off slips on the fridge magnet, were particularly important components of the package. They acted as a catalyst in helping participants consider new ways to increase their PA:

*... fascinating ... Erm, well just really interesting to find out what I do every day and if I do, do something different what impact that has, what the result of that is and it does encourage me to think, erm, right I'll get up and go and do whatever, anything, erm, and it makes me think in a different way about doing things.*

P09

*A, erm, and it makes me think in a different way about doing things because, for instance, my doctor's is, err, a bus ride, it's awkward for me to say to my family 'can you take me?', I'm sort of now starting to think since I've got a bit more energy, my, erm, my legs are working better if you like, I'm starting to think along the lines of, well I can catch a bus and then walk the rest of the way, I don't need somebody to take me and it will, that will certainly increase my steps ...*

P09

Although the aim of achieving or exceeding step goals was motivating, the desire to avoid not meeting these goals was also motivating and participants would set their goals to avoid feelings of failure and/or guilt, with one participant using paper-based goal-setting to avoid setting goals online with e-coachER:

*Yeah, about, like, I say, like, you keep them realistic don't you? So you don't, you don't set yourself up to fail.*

P04

*I haven't as yet put anything down on e-coachER, simply because I put down on a piece of paper what I hope to do on a given week and failed miserably to do them so I thought I didn't want to start to put them down, erm, until I knew that they were reasonable goals that could be achieved, not pipe dreams that have got no chance of being achieved.*

P01

Participants generally felt that e-coachER provided a reminder to think about being more physically active, for example from the fridge magnet with tear-off PA-recording strips and use of the pedometer:

*Every day I, well at the end of every day, I look at the pedometer and say 'oh OK you've exceeded your goal'.*

P04

*It's just it's another tool that you can use to, you know, either monitor or encourage or, you know, everyone works differently I suppose and I didn't, what I needed was something concrete, goal-wise, to do and to achieve and like I say, you know, once I'd set that goal then and if I don't reach it well shame on me kind of thing.*

P16

However, it became clear these aspects of the intervention were often used only initially and then some people switched to using their phones or other devices to record activity:

*I would say so, even though I'm not doing it on the, erm, website now 'cos I monitor my step counts through my phone.*

P15

Some participants felt that the e-coachER package was instrumental in helping to ameliorate any feelings of guilt experienced when participants perceived their efforts to increase PA were in some way unsatisfactory. For example, the reiteration that failing to meet set goals is normal and something that should be expected, which occurred later in the steps to health (the 'slips, trips and falls'), was particularly helpful for some:

*Being someone who suffers from depression, I understand about triggers and setbacks . . . But you know this part of the system is explaining to you that it's OK, don't worry about it, there are always going to be times in your life where you're not going to be able to do this and you shouldn't beat yourself up too badly about it.*

P01

Participants reported that being able to choose their preferred level of engagement with e-coachER was a valuable feature and allowed participants autonomy over their exercise choices:

*Oh, [I would] definitely recommend it. Like I say, I know that I haven't engaged with it as well as I could have but the point still stands that it was instrumental in that motivation at the beginning of going and doing it and doing exercise referral and setting those goals and trying to maintain achieving those goals each day and then obviously upping them and it's definitely worth it.*

P16

Use of e-coachER also had the potential to help participants to develop or expand social networks conducive to augmenting PA:

*It gives you different tips and tells you who to ask and different sites to get in touch with. I went to an osteoporosis meeting and they do an exercise thing and you can actually become a teacher with a qualification eventually but, like I say, I can't do anything like that at the moment. . . . they give monthly talks and they have someone come to visit to give a talk who works and specialises in osteoporosis and . . . and they do an exercise group once a week. . . . so it's quite good really.*

P06

However, many participants felt that they already had an adequate social support network:

*I've already got quite a good support network, so I just utilised my work colleagues.*

P14

### Improvements to e-coachER

Many participants felt that e-coachER could offer more in terms of functionality and that it did not provide as much information or as many features as could readily be obtained from other 'app'-based packages. For example, some participants felt that the package was not interesting or did not provide enough information and some were disappointed by these shortcomings. Some felt that e-coachER did not work in the way that they had expected, or were frustrated by being locked out of the website rather than being able to progress on to the next stage when they were ready to do so:

*I think you know, erm, the website is useful, erm, albeit frustrating at times but once . . . I get past step 7 I might have a different view about that because I won't be locked out then or I would think not, I don't know.*

P12

Others found that the e-coachER website was 'not that inspiring' (P12) or 'drab' (P03) and one participant referred to it as 'death by PowerPoint' (P04). A number of participants described the website or aspects of it as 'confusing' (P02), 'annoying and irritating' (P07) or not 'smart' enough (P04). Participants went on to offer suggestions for improvements to e-coachER, which are summarised in Table 19.

TABLE 19 Suggestions for improvements to e-coachER

Topic	Summary of problem and/or suggestions for improvements	Participant quotations
Welcome pack	The lack of language options in the information pack and the lack of options regarding disabilities was highlighted	<i>I don't see any foreign language on it. In terms of diversity I don't see any Arabic, Chinese, Punjabi erm ... Whatever so you can have this leaflet in X, Y or Z</i> P04
	Although straightforward in terms of ease of understanding and clarity, some felt that it did not look interesting or engaging	<i>User manual should be made more visual ... It didn't inspire me to turn the page ... It is I mean it's not a huge criticism when I say that, I don't mean that as it perhaps sounds it's not a huge criticism, it is a bit dull ... I mean I read it because I had to but I didn't enjoy it, erm, and you know, I wonder if how many people are skipping over it</i> P05
		<i>... I suppose really it's got to be generic but ... if you're a woman I would like it, sort of, a little bit more interesting just ... it just may be needed to be a little bit more eye-catching I think I'm trying to say</i> P18
Website design, logging on, access and navigation, and lock-out	Although many found that the e-coachER website was easy to navigate and use, many found the layout of the package and being logged out at certain predefined points frustrating and found navigation difficult and restrictive	<i>... I thought it would be very helpful if you could see what every stage was and then go back to where you were rather than having the situation where you're in a stage and you can't go onto the next one. ... but at the moment of course you can't move on without being locked out ... with the website, you know, I'm not technically in control of what's on the other end so it's sort of going in and having a good look round and seeing what you can and can't do</i> P01
	More tailored website was suggested (e.g. could be split up into different categories of condition for referral)	<i>I think at the front end of the e-coachER it might be a wider remit and then take it out from the tree stem and then branch off so that if it's obesity you can look at different goals, if it's diabetes again and if its mental health but it's splitting them up from each other</i> P04
	A minority of participants experienced IT-related problems, logging on, passwords, accessing e-coachER, etc. These were not difficult to resolve and logging on was straightforward for most. Some commented that logging on could have been made easier as participants had to go through the original e-mail link. Some felt that further developments regarding mobile access would have improved e-coachER. Some differences in the experience of e-coachER using different platforms [e.g. one participant reported not being able to access links using an iPad (Apple Inc., Cupertino, CA, USA)]	<i>So I think again that would be something to say if you are having trouble if you use I don't know iPads, Mac [Apple Inc., Cupertino, CA, USA] other things just click on the link and it will take you to it</i> P04  <i>It was suggested that 'well you've got to do it through Microsoft [Microsoft Corporation, Redmond, WA, USA], you've got to do it through this, you've got to do it through that' ... I don't know if it would actually work with a Mac</i> P04

TABLE 19 Suggestions for improvements to e-coachER (continued)

Topic	Summary of problem and/or suggestions for improvements	Participant quotations
Stage 1 quiz	Many felt that the quiz did not offer new information	<p>No, I mean I'm not putting myself up as a genius but some of it is at quite simplistic level P03</p> <p>Erm, going through the quiz saying, you know, 'did you realise that', ah, but you know 'if you did this', it did feel rather high school-ish P05</p>
Stage 2 links to finding support	Some found links for external and additional support out of date or irrelevant. Although some found the links thought-provoking, few directly benefited from using these links	<p>Some of the information that I was looking at was actually dated for last year and all the classes weren't up to date P18</p>
Pedometer	<p>The pedometer did not always tally with other devices</p> <p>Some found that the pedometer was difficult to open; some found that it was difficult to wear</p>	<p>The pedometer seemed to just do its own thing. It stopped logging them properly... again the next day it was the same sort of thing P06</p> <p>The other thing I've found quite tricky was getting it placed properly... Sometimes it was a bit uncomfortable P04</p> <p>I am using my own [fitness tracker] anyway just purely because I think I said to you before with the pedometer it suggests that you put it on your waistband well women and maybe for men I don't know, don't always wear things that are suitable for the pedometer and so it would be easier if you could use whatever other means you have, if you have that P24</p>
Entering step count onto e-coachER website	Inputting steps on the website required participants to round up or round down, which may negate the message perceived by many that 'every little bit helps'. Some felt that the step count should accurately reflect the number of steps achieved	<p>I think it would be quite useful if you could put in the actual steps you've done rather than, erm, rounding it to the 500. Because I, well this morning, I put mine in and I'm a very honest person and if I've only done 3200 I'm not going to put in 3500. I'm going to put in 3000 but that in itself can be a little bit, erm, disappointing because you think well actually I've done a bit more than that P09</p>
Reminder e-mails	Did not factor highly as a necessary component of e-coachER; some found that these reminders were unhelpful or did not reflect their actual engagement	<p>Erm, well I've been logging in every few days but, erm, apparently I kept getting e-mails to say, erm, where have I been and 'it's been 4 weeks since we heard from you' P06</p> <p>The next day I'll get one 'oh we noticed you haven't logged in for 1 week' and what would help is perhaps when one sets one's goals that a date was inserted so there's no argument about that P03</p>
continued		

TABLE 19 Suggestions for improvements to e-coachER (continued)

Topic	Summary of problem and/or suggestions for improvements	Participant quotations
Later steps: setting goals and dealing with setbacks	Later steps used less frequently. Those who engaged with the later stages of e-coachER found that goals were not always saved	<i>What I found frustrating ... it completely wiped what I'd put the week before ... for me once I get into the routine I can generally do the same activities just adding more in and virtually review them but you have to input absolutely everything again plus the extra stuff that you were doing that week. And I don't I think, you know, it wouldn't take much for that information to pull through and you just amend it. Rather than rewrite it each week and if you're going to set up completely new goals that's absolutely fine but actually, you know, you should be able to, it would be better to pull it through and amend it ...</i>
	One participant suggested that support regarding 'slips, trips and falls' may be better placed at an earlier step	P14
	Goal-setting sections could be more 'inspirational'	<i>That message coming at the end if you like although I know it's not the end of e-coachER but it's the end of the steps. If it was in earlier ...</i>
General	Lack of interaction with health professional or 'real person'	<i>It's good to have inspirational stuff to help you along ... It wasn't inspirational in any way the [web]site, you know, because you can have goals and you can have inspiration, sort of, pushing you towards the goals</i>
		P07
		<i>Yes, yeah maybe, I don't know, 2 or 3 weeks or even 4 weeks down the line, you know a conversation with somebody just even if it's just to see how they're getting on. 'How are you getting on, how are you finding it?' ... if somebody is struggling and they've thought 'oh no I can't do this' in the early days then you would have picked them up already, do you get what I mean? ... Just to have somebody there as well as on the computer sort of thing, have a bit more of an input earlier on that's great. As much as we are embracing the technology of life and all the rest of it, there is nothing more valuable than a voice and like talking to you</i>
		P21

### e-coachER as a support for exercise referral scheme use and uptake or as an alternative to exercise referral schemes

The aim of the e-coachER package was to support and enhance the uptake of ERSs:

*And I think what ... e-coachER did was it acted like a prompt. So, I suppose in terms of my own personality I don't like to let people or anybody down so if I had an appointment with the practitioner I would make sure I got there or try my damndest you know what I mean.*

P19



One participant described a lack of support from the ERS and that e-coachER was able to mitigate the effects of this:

*Because with the exercise referral scheme ... I had to do things myself, if that makes sense and I went and I had my induction, she, there was, there was no come back to say 'how are you getting on, how are you finding things?'. The person that did the induction with me hasn't been in touch with me again, whereas at least with the e-coachER I can refer back to it. I can look at it at my leisure and go back and be inspired again. Whereas I had, I've not had that contact with the person at the gym.*

P21

Although the combined use of ERS and e-coachER was noted, a number of participants reported that they found the ERS difficult to commit to, perhaps more so than other self-selected activities, whereas others expressed a lack of interest in the types of exercise being offered. There were other difficulties for some participants in accessing the facilities or services being offered by the ERS. These included geographical location, transport issues, gym costs, the participants' working patterns or problems with ERS oversubscription and delays in the referral process or staffing levels. In addition, other barriers to ERS attendance stemmed from unforeseen individual circumstances (e.g. bereavement, injury and other health issues). e-coachER was therefore an important alternative or seen as separate to ERS:

*It just feels like they're two different things because I don't always see my instructor all that much and I don't know what, how that works.*

P18

## **Trial research assistants' experiences and role in recruiting and supporting participants through e-coachER**

### ***Research assistants' suggestions for improvements to trial recruitment processes***

Researchers suggested that a more direct approach to recruitment would improve rates, for example (1) using more refined criteria for identifying possible participants and (2) using study researchers to carry out this task:

*They looked at the databases and contacted like hundreds of patients who they thought were eligible for e-coachER and they had a really poor return. I think to be cost-effective we're going to have to be very clear and definite about finding the right criteria. [...] So I feel that that's going to be a big way forward is the clinical research network or somebody in the research field is going to be able to, have to go into practices and have access to the databases and pull, going, doing that directly rather than asking the GP to spend part of his valuable few moments that he has with patients trying to encourage them to take part in a research study. That's not going to happen, they just, although they are willing to do it they just don't have time to do it.*

RA02

Broadly, simplifying the referral and paperwork, streamlining the referral system, contacting participants via the ERS rather than via the GP, or contacting the participants directly about the study after the ERS practitioner had sought permission to pass on contact details to the researcher were found to be helpful:

*We had approval to go straight to the exercise referrer who was receiving the exercise referral from the GP and then ask the staff there to help us identify the people that would be suitable for our study looking at our study criteria and then approach them to either get, give consent for the patient to pass on their telephone details to me as the RA [research assistant]. And then I would either approach them directly or she would give them out the patient, the trial information pack and then the patient could contact me if they were interested in taking part and that was really successful.*

RA01



Similarly, at another research site, opportunistic sampling via general practice was slow. Engaging the ERS team to help gave little opportunity for researcher–participant interaction, but a significant improvement in recruitment rates:

*So opportunistic recruitment didn't work well at any point for us but the ERS, using the ERS system mailout out to potential participants, that worked really well. I mean we really, we kind of went from way behind to meeting our recruitment targets from the ERS, so they were really helpful.*

RA03

*Opportunistic recruitment it was very slow and it was also, I was constantly, kind of, chasing and reminding the GPs. Whereas with the ERS, it was one of the data team who was sending out the packs and she, you know, she just had to input the data and it was really a small job for her just to send out a letter to any potential participants. So, it was really, it worked much better, it was much more fluid.*

RA03

### **Research assistants' suggestions for improvements to the e-coachER package**

As with the study participants, researchers felt that there was some scope to refine e-coachER in terms of functionality:

*I guess I mean there was a couple of people that had said that the website should have been a little more, I don't know, maybe all singing all dancing sort of thing. I think the competition is now with all these devices, apps and things that are out there, a lot of people were maybe, well not a lot, a couple of people had flagged up that they were disappointed with how basic the website is. On the flipside of that, it does need to be basic because a lot of people aren't computer literate but I guess that's a downside with the competition now from all the apps and so many things that are out there that it maybe does look less appealing.*

RA02

### **Research assistants' views of participants' attitude towards the trial**

The researchers felt that most participants were already highly motivated to take part in something (the research) that would help them to make lifestyle changes and increase PA. Although it was less clear that they had understood why they had been referred to an ERS, there was some confusion regarding being contacted about the research study and being referred to an ERS:

*I think they were all quite positive really. There were obviously some people who just weren't interested but the main thing that came out when I've been looking into it, there was a lot of confusion over what they'd actually been referred to. So there was a lot of the times I had to explain that they'd been referred by their GP and that it was the [exercise referral] scheme and I had to explain what that was but, generally, once they kind of knew what we were doing in conjunction with that, they were very positive ... I think they were all interested in doing something that helped them and a couple of them were even, you know, I think also the voucher, obviously that was a nice bonus to have but yeah they were all very positive about doing it.*

RA03

One further finding relating to participant experiences of being in the research trial arises from both the research assistant interviews and from a final follow-up interview with one of the participants, who remarked that just having the interview was 'motivational' (P13) as it was:

*... another reminder that I need to go back to e-coachER to keep it there so you're you [the research interviewer] are part of the motivation.*

P13

The research assistants also noted that participants using e-coachER often described the importance of social support, and at times either explicitly or implicitly mentioned the support obtained from the researchers (including the qualitative interviewers). Two of the researchers commented:

*Again, it wasn't something that we have discussions with because it wasn't part of my role, however, I did get some e-mails from a lot of people who just felt that they wanted to tell someone that they were logging their steps. Although they didn't have to, a few participants have done that, it was a very important aspect to them.*

RA02

*A lot of participants said it was nice to have me on the phone to contact, so it's not just online. ... I think a lot of the people when they fill in the website they phoned me after to say why they haven't been as active ... this week because, this month because they'd been, you know, had an injury or they'd been busy and I think it was just that, that kind of option to explain that they don't get via the website.*

RA03

## Discussion

The qualitative component of the process evaluation helped to develop a better understanding of the participants' experience of and engagement with e-coachER and to explore how factors both related and unrelated to the e-coachER contents affected participants' engagement with ERSs and the e-coachER website itself. A further element was to understand the experiences of the researchers working on the e-coachER trial. The findings are also of relevance beyond the e-coachER RCT, in particular regarding the role of support, self-monitoring, goal-setting and feedback from IT support tools. Interviews with members of the trial site teams involved in recruitment provided further information regarding trial implementation and delivery.

The e-coachER intervention went through substantial initial piloting with public and patient input prior to going live within the trial and some specific features of the intervention were designed for a purpose. For example, the lock-out feature of the intervention was aimed to prevent participants going through all seven 'steps to health' in the same session, which would leave less reason to return to the website at a later date. It was inevitable that some participants found this frustrating or worthy of comment, such as the useful suggestion that relapse management ('slips, trips and falls') would have been helpful at an earlier step. Strategies that prevent existing, or developing, competencies from being undermined were an important feature of e-coachER's design and the 'slips, trips and falls' step was instrumental in helping participants to develop and maintain competence rather than experience failure. However, potential opportunities to develop competence by engaging in these later steps were often not realised as participants found these stages less 'user friendly' than earlier steps or were not able to proceed onto these steps when they wanted to, having been automatically locked out in the earlier stages. Being locked out of the package may have provoked annoyance and disengagement and may have a negative impact on the control/autonomy dimension of self-determination theory. It should be noted that these findings arise from the relatively few participants interviewed who reached these end steps.

We also designed the intervention to engage with participants with a range of levels of IT literacy. However, for those interviewed it was clear that most were competent IT users, meaning that, for some participants, e-coachER provided insufficient content and functionality. Similarly, information provided in e-coachER was designed to be straightforward and accessible for all, for example the quiz, sometimes described as a 'useful reminder', seemed to serve as a prompt to remind participants what they 'should' be doing. Thus, although little of the information was considered to be new, the reiteration appeared to be valuable and some felt that the links provided useful information but others found that it was too basic, perhaps offering insufficient challenge to allow the development of a sense of competence around using e-coachER. It is clear that although some participants appreciated the information provided, there is scope to add further levels of information and advice as this would both allow

tailoring for specific conditions and help to create a sense of progression (of information detail) within e-coachER. It is possible that the efficacy of the intervention may vary depending on the condition for which the participant was referred, and many had multiple comorbidities. More tailored information, which could be selected if relevant, may have added to the functionality of e-coachER and provided further opportunities for the user to develop feelings of competence regarding undertaking more PA with their underlying health condition. In the future, the intervention could be refined to include more explicit statements about the intervention design features (e.g. the purpose of the lock-out, that the pedometer is only a basic monitoring tool) as well as provide more optional levels of information content related to specific health conditions.

Interviewed participants identified two main 'active ingredients' of e-coachER. The first was the skills training and opportunity to set goals and to monitor progress by using the pedometer. This encouraged participants to reach or exceed their personal goals. Goal-setting and self-monitoring have been found to facilitate the ability to initiate and maintain behaviour change.<sup>29</sup> The participants who were interviewed did seem to set their goals realistically and they were broadly SMART; they 'set their pace' and mentioned how setting and attempting to meet these goals were positive aspects of the intervention and participants particularly valued the step-count activities. Donnachie *et al.*<sup>60</sup> also described how pedometers can provide tangible evidence of progress and demonstrate enhanced competence, with the device being seen as an 'ally' to meeting goals. It was clear that participants appreciated receiving the pedometer (and fridge magnet) and recent research has shown that providing primary care patients with a pedometer by mail is effective in increasing PA,<sup>61</sup> so this finding was not surprising. However, although most participants were very enthusiastic about obtaining feedback from the pedometer, some were disappointed by the quality of the device and wondered if the step count was accurate. Whether or not these limitations acted as barriers to engagement with the e-coachER or the PA (or both) is unclear, although previous research suggested that mistrust of monitoring equipment may be detrimental.<sup>59</sup>

Second, the provision of support, for example by providing a virtual 'reminder' or 'pat on the back', was regarded as an important aspect of e-coachER. These features provided opportunities for social interaction and/or the support of social interaction where social interaction had been in some way lacking. The e-coachER intervention, grounded in self-determination theory, sought to build a sense of connection or relatedness with others. Throughout the interviews, participants referred to the importance of social support and how this was met to varying degrees through e-coachER. Step 2 of e-coachER encouraged participants to seek social support, highlighting opportunities for joining groups, communities, discussion forums, etc. Although designed to be specific to the participant's geographical area, some felt that these were not relevant to their needs or could be improved in other ways. For other participants, however, e-coachER did help to facilitate an open discussion about health within the participants' social network and provide them with an initial starting point or 'trigger' to try new things. The concept of competence refers to an individual's need to master tasks or to learn new or different skills,<sup>31</sup> and some participants described how e-coachER helped them to develop the confidence to engage more with PA.

In general, most participants reported at least some benefits of using e-coachER; participants often felt that its use was 'motivating' but when asked to explain more they were less clear in identifying which specific aspects had this motivating effect. A qualitative study evaluating the effects of a walking intervention found that many participants reported benefits of trial participation, even when objective quantitative measures of PA did not increase.<sup>59</sup> Although satisfied with the e-coachER website providing a 'starting point' for their plans to increase PA, many found the limitations inherent in the e-coachER package to be frustrating. For example, it is possible that the e-coachER prompts (if inappropriately timed) undermined intrinsic motivation and this may have been compounded by a reduced sense of control arising from being locked out of e-coachER for predefined periods of time.

A number of participants felt that components of e-coachER were limited or could be improved, but they often described the package as a valuable resource. This may be because participants were already motivated to make changes and e-coachER provided additional support to do this. Many of the participants had actively sought to attend ERSs and described a pre-existing motivation or readiness to change.<sup>62</sup> Those who reported few benefits from e-coachER may not have been at a stage where they were ready to make changes and it is also possible that, over the duration of the engagement with e-coachER, participants progressed non-linearly through stages of readiness to change. None of the participants explicitly stated that they were not motivated to increase their PA and most were positive about their involvement in the trial. They felt that they were supported by an intervention that was designed to help them to achieve greater levels of PA and felt that e-coachER consolidated, directed and focused their desire to make changes.

### **Strengths and limitations**

Interviewing participants at different stages of engagement with the intervention, and the follow-up interviews with seven participants, allowed us to tap into experiences at particular stages of e-coachER and, for those giving repeat interviews, how perceptions may have changed as engagement progressed.

The present findings were prepared blind to overall trial findings before being presented at a trial management meeting. This strengthens the findings from the qualitative research as the main trial results did not influence the interpretation of the qualitative findings.

One limitation is that the extent to which the interviews and the support provided by the research assistants may have affected the participants' interaction with e-coachER is unclear. However, most of those interviewed had only one interview ( $n = 19$ ), and these contacts were relatively early on in the intervention period. Furthermore, we could find no obvious differentiation between interviewees who had one interview and those who had multiple interviews regarding their comments about engagement with the other intervention components. Moreover, given the absence of a difference in the primary outcome and most other outcomes in the trial, it is unlikely that a few additional interviews had any influence on the findings.

It is also unclear whether or not the participants' appreciation of being in the 'additional' intervention group affected their responses to the interview questions and to e-coachER as well. Some were apologetic about being critical of the intervention components and participants may have felt obliged to modify their criticism.

None of the 16% of the total e-coachER study sample ( $n = 450$ ) who were classified as having low IT literacy (as a stratification variable) was interviewed and this may have limited our ability to understand how the web-based support helped or did not help these participants. This is a limitation but does not necessarily mean that we interviewed only those with very strong IT skills.

We did not interview any participants who were not in the e-coachER group of the trial about their experiences of ERSs. Therefore, we do not know how trial control group participants felt about not being selected for the intervention group or about their experiences of ERSs. A further limitation is that we did not interview any participants at the end of their time in the trial, for example at about 12 months post enrolment, to explore their experiences over the longer term and whether or not e-coachER had helped them maintain PA levels. Interviewing at this time point may have provided a clearer picture of the extent to which any behaviour change achieved during interactions with e-coachER were sustained. However, undertaking such late-stage interviews could have compounded the co-intervention effects already mentioned and resources were not available to conduct such interviews after the primary end point of the main trial.

## Conclusions

There has been considerable literature on the barriers to and facilitators of ERSs, so the qualitative work focused mainly on if and how the e-coachER intervention complemented usual ERSs. The e-coachER intervention was acceptable and was positively experienced by many of the interviewed participants, and enhanced competence, autonomy and relatedness for many, but not all of the interviewed participants, with several areas for enhancement and augmentation identified. Engaging in self-monitoring and progressive goal-setting helped to build a sense of competence to increase PA. In doing so, participants appreciated the opportunity to make personal decisions about the types of activities they engaged in and how often. The website encouraged participants to get personal support from the ERS and this worked for some but not others, for example those who had other competing demands on their time. We were not able to identify specific examples in the interviews of how the website had brought people together to share PA experiences. There were positive and negative experiences of e-coachER but these were not necessarily of equal impact. For example, finding e-coachER a useful reminder to exercise may have more positive impact than the dislike of the web page layout or colour scheme. Instead of focusing only on individual positive and negative experiences of e-coachER itself, it is perhaps more important to place the findings from the interview study into the wider context. This was a complex intervention and, as such, may be more or less effective for individuals depending on their morbidities or comorbidities, complex personal circumstances or whether or not they were ready to increase PA.

For future trials, it is important to ensure that recruitment and referral pathways are as direct, targeted and straightforward as possible (i.e. not dependent on busy general practices). Future trials could be resourced sufficiently to allow any parallel qualitative study to be balanced across trial groups.

## Quantitative process evaluation

### *Aims and objectives of the quantitative process evaluation*

Within our logic model, we expected that the e-coachER support package would more favourably influence some key theoretical components (i.e. a sense of competence, autonomy and relatedness, and heighten value or importance attached to the behaviour) and behaviour change processes (i.e. action-planning, self-monitoring, enlisting social support) known to be involved in health behaviour change.

The objectives were to explore whether or not:

1. the e-coachER intervention led to more favourable process outcomes compared with usual ERS alone at 4 and 12 months
2. any changes in the process outcomes between baseline and 4 months (during which intervention engagement was expected to predominantly take place) mediated any intervention effects on the primary outcome [i.e. minutes of accelerometer-recorded MVPA (in bouts of  $\geq 10$  minutes) at 12 months].

## Methods

The survey used to capture the process outcomes was described in *Chapter 2*. Briefly, items were derived from extensive reviews of the literature to ensure that they matched our expected changes within our logic model but also were fit for purpose within a RCT. In other words, they had to make sense for a responder whether or not they did any PA and they had to have some sensitivity to identify change. In response to PPI input, we also had to maximise the participant completion rates so we ensured that the questions were easy to interpret and the response format was clear. The items and respective scales are supplied in *Report Supplementary Material 4*.

Questions about importance and confidence are single items using an 11-point scale. The remaining items were chosen to represent specific constructs and create composite scores. Confirmatory factor analysis revealed support for adding survey items to assess: perceived competence in being regularly

physically active (four items), autonomous in decisions about PA (four items), availability of support (three items), frequency of support (three items), action-planning (five items) and self-monitoring (two items). The Cronbach's alpha coefficient of all factors were found to be in excess of 0.77, indicating good internal consistency of each. Composite scores were calculated and used in the analysis.

Using a model adjusted for age, gender, stratification variables and baseline scores, and random effects for centre, with only participants included in the primary analysis (i.e. based on complete accelerometer data and had completed the respective survey items), we compared each of the eight process outcomes by group at both 4 and 12 months. We restricted the analysis to outcome data deemed valid, with no more than 200 minutes spent in 10-minute bouts of MVPA, as per the primary analysis.

The size and significance of any mediating effects were evaluated through the product of coefficients method.<sup>63</sup> This was performed irrespective of the results from the main analysis, as mediation may still be possible without having detected a significant effect of the intervention on the primary outcome.<sup>64</sup> Referring to the causal diagram in *Figure 6*, the coefficient, *a*, for the intervention effect on process measures in path A was derived from the mixed model of changes in process measures regressed on the intervention, adjusted for age, gender, stratification variables and random effects for centre. Utilising the same adjustment variables, the coefficient, *b*, for the change in process measures on the primary outcome in path B was obtained by modelling the outcome on the process measure change, also adjusting for the effect of the intervention. The coefficient of the mediating effect was, therefore, calculated as the product  $a \times b$ . The CIs were calculated using the Sobel test,<sup>65</sup> dividing the coefficient product by the estimated standard error used:

$$SE_{ab} = \sqrt{(a^2 \times SE_b^2 + b^2 \times SE_a^2)}. \quad (1)$$

## Results

Descriptive data are shown in *Table 20* for each of the eight outcomes at baseline and 4 and 12 months, by trial group.

Analysis of the intervention effect on the process outcomes among participants meeting the minimum accelerometer wear-times as specified for the primary analysis indicated that intervention participants reported greater change in beliefs from baseline to 4 months for PA beliefs about importance, confidence and competence than the control group (*Table 21*). By 12 months, there was no longer evidence of differences in change in beliefs between the intervention group and the control group.

*Figure 6* shows the a priori model to be tested in the mediation analysis.

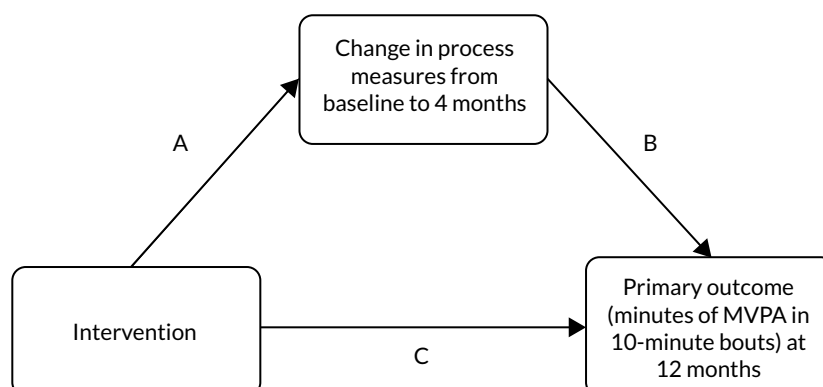


FIGURE 6 A priori path model for testing mediation effects.



TABLE 20 Descriptive data for all the process measures among only those included in the primary analysis

Mediators	Baseline		Month 4		Month 12	
	Control, n, mean (SD)	Intervention, n, mean (SD)	Control, n, mean (SD)	Intervention, n, mean (SD)	Control, n, mean (SD)	Intervention, n, mean (SD)
1. Importance	121, 5.49 (2.90)	96, 5.58 (2.58)	117, 6.53 (2.76)	95, 7.55 (2.22)	122, 6.34 (2.77)	100, 7.14 (2.55)
2. Confidence	121, 5.60 (3.10)	97, 6.06 (2.73)	117, 5.56 (3.28)	95, 6.72 (2.82)	122, 5.44 (3.28)	100, 6.07 (2.94)
3. Competence	123, 13.14 (3.65)	97, 13.74 (3.46)	113, 12.69 (3.92)	93, 14.27 (3.64)	118, 12.51 (3.94)	99, 13.40 (4.09)
4. Autonomy	121, 14.26 (3.48)	98, 14.54 (3.18)	116, 14.69 (3.64)	93, 15.31 (3.31)	121, 14.53 (3.45)	96, 15.32 (3.41)
5. Support availability	122, 9.89 (3.39)	97, 10.47 (2.93)	115, 9.77 (3.38)	94, 10.80 (2.87)	121, 9.69 (3.30)	97, 10.36 (3.18)
6. Support frequency	122, 7.01 (3.50)	99, 7.61 (3.17)	116, 7.58 (3.62)	94, 8.03 (3.41)	120, 6.97 (3.62)	100, 7.70 (3.38)
7. Use of action-planning	117, 12.99 (5.25)	97, 13.13 (5.03)	114, 16.10 (5.00)	92, 17.09 (4.67)	120, 14.84 (5.19)	97, 15.88 (4.91)
8. Use of self-monitoring	121, 5.17 (2.16)	98, 5.70 (1.97)	115, 6.60 (2.02)	94, 7.36 (2.03)	121, 6.32 (1.95)	99, 6.70 (2.09)

Greater values reflect more positive beliefs.

1. Perceived importance of doing at least 30 minutes of moderate-intensity PA (e.g. brisk walk) on at least 5 days per week (using 0–10 scale: 1 item).
2. Confidence in achieving at least 30 minutes of moderate-intensity PA (e.g. brisk walk) on at least 5 days per week (using 0–10 scale: 1 item).
3. Perceived competence in being regularly physically active (using 1–5 scale: 4 items).
4. Autonomous in decisions about PA (using 1–5 scale: 4 items).
5. Availability of support (using 1–5 scale: 3 items).
6. Frequency of support (using 1–5 scale: 3 items).
7. Action-planning (using 1–5 scale: 5 items).
8. Self-monitoring (using 1–5 scale: 2 items).

TABLE 21 Intervention effects on changes in process outcomes from baseline to 4 and 12 months

Mediators	Month 4				Month 12			
	n	Coefficient	p-value	95% CI	n	Coefficient	p-value	95% CI
1. Importance	208	0.888	0.013	0.184 to 1.592	218	0.705	0.098	–0.129 to 1.540
2. Confidence	209	1.041	0.007	0.287 to 1.794	219	0.393	0.332	–0.401 to 1.187
3. Competence	205	1.214	0.024	0.158 to 2.269	216	0.571	0.337	–0.593 to 1.735
4. Autonomy	207	0.51	0.306	–0.466 to 1.486	216	0.495	0.335	–0.511 to 1.500
5. Support availability	208	0.399	0.318	–0.384 to 1.182	216	0.026	0.951	–0.818 to 0.870
6. Support frequency	211	–0.072	0.889	–1.090 to 0.945	220	0.115	0.831	–0.947 to 1.178
7. Use of action-planning	200	1.249	0.18	–0.575 to 3.073	210	1.042	0.239	–0.694 to 2.777
8. Use of self-monitoring	209	0.293	0.45	–0.468 to 1.054	218	–0.102	0.774	–0.798 to 0.594

Table 22 shows the analysis of mediating effects of change in the process outcomes (from baseline to 4 months) on the primary outcome at 12 months, using only participants included in the primary analysis. There were no significant mediation effects. Despite there being significant intervention effects on change in beliefs about importance, confidence and competence at 4 months, these changes in beliefs did not translate into increases in MVPA minutes at 12 months. A possible explanation is that the intervention effects on the primary outcome were insufficient to fully test the mediating effects, especially given the distributions, with many participants recording zero for minutes accumulated in bouts of  $\geq 10$  minutes. Another explanation may be that the 10-point scales used to assess importance and confidence were more sensitive to identify change than a 5-point scale used for the other outcomes.

Nevertheless, according to analysis of path B in the mediation diagram (see Figure 6), the primary outcome did appear to be sensitive to changes (from baseline to 4 months) in importance, the frequency of support, action-planning and self-monitoring. However, in all but importance, there were insufficient changes to assume a mediating effect in the process measures between baseline and 4 months. With regards to importance, although paths A and B were individually significant, the combined change in this process measure and its effect on the primary outcome according to the Sobel test was insufficient to produce a significant mediating effect.

## Summary

Our mixed-methods approach to understanding if and how the intervention worked for some participants provided interesting insights into engagement with a novel technology-based support system and how that complemented the available support from usual ERSs. The qualitative and quantitative approaches were conducted independently. The interviews highlighted the role of developing self-monitoring and SMART goal-setting skills to increase confidence, which featured strongly in being physically active on a regular

TABLE 22 Mediation effects for the process outcomes

Mediators	n	Path A		Path B		Mediated effect		
		Coefficient (SE)	p-value	Coefficient (SE)	p-value	Coefficient (SE)	95% CI	p-value
1. Importance	204	0.919 (0.365)	0.012	2.483 (0.924)	0.007	2.282 (1.242)	-0.152 to 4.716	0.066
2. Confidence	205	1.056 (0.392)	0.007	1.433 (0.832)	0.085	1.513 (1.043)	-0.531 to 3.557	0.147
3. Competence	201	1.139 (0.547)	0.037	0.267 (0.614)	0.664	0.304 (0.714)	-1.095 to 1.704	0.670
4. Autonomy	203	0.478 (0.508)	0.347	0.437 (0.679)	0.520	0.209 (0.393)	-0.561 to 0.979	0.595
5. Support availability	204	0.419 (0.407)	0.303	-0.104 (0.820)	0.899	-0.044 (0.346)	-0.722 to 0.635	0.899
6. Support frequency	207	-0.065 (0.527)	0.903	1.568 (0.598)	0.009	-0.102 (0.827)	-1.723 to 1.519	0.902
7. Use of action-planning	196	1.198 (0.938)	0.201	1.012 (0.362)	0.005	1.212 (1.044)	-0.834 to 3.259	0.246
8. Use of self-monitoring	205	0.235 (0.389)	0.545	2.533 (0.828)	0.002	0.595 (1.004)	-1.373 to 2.563	0.553

SE, standard error.



basis. The survey process outcomes confirmed that the intervention increased importance and confidence up to 4 months but the effects (compared with usual ERSs) had dissipated by 12 months.

The qualitative interviews were mostly not able to follow intervention participants for long. The lack of intervention effects on changes in other process outcomes (e.g. action-planning and self-monitoring) was surprising given that 36% of the participants reached step 5 (completed a goal review). Some participants continued to complete goal reviews for up to 12 months, but it would appear that an insufficient number of participants did so, and most had stopped completing goal reviews long before completing the 4-month follow-up assessment. This was also despite periodic reminders from the online system to log in.

The interviews provided a little information on how e-coachER had prompted intervention participants to find and use social support to increase PA (e.g. support to get active – step 2). Although designed to be specific to the participant's geographical area, some felt that the e-coachER links to other PA opportunities were not relevant to their needs. For other participants, however, e-coachER did help to facilitate an open discussion about health within the participants' social networks. It is possible that simply talking about being in the e-coachER study (i.e. an opportunity to connect) would have been done by participants in both of the trial groups and few actually got around to joining groups or setting plans to exercise with others. Hence, this may explain why the intervention had no effects on the process outcomes, namely identifying and using social support.

In this pragmatic trial, the aim was to determine if there were intervention effects in addition to usual ERSs. An alternative explanation to null intervention effects on some of the process outcomes is that usual ERSs have sufficient positive effects on PA beliefs to make additional effects unlikely. The Glasgow ERS differed from the other ERSs involved in the trial, in that the exercise professional supported participants with behaviour change counselling and signposting to different PA options. In this sense, the Glasgow ERS may have been expected to build a sense of autonomy and the e-coachER support may not have added much. Further analysis is needed to explore differences in intervention effects on process outcomes by site, although site did not interact with the intervention effects on the primary outcome. Health interventions, including ERSs, are notorious for having short-term effects on health behaviour that dissipate with time. Given that ERSs can provide barriers to engagement and sometimes may not promote a range of sustainable PA options, we designed e-coachER to have more lasting appeal and to develop self-regulatory skills and the intrinsic motivation to be physically active for managing chronic conditions, above and beyond usual ERSs. Some key processes did change as a result of e-coachER engagement in the short term but these were not sustained, which is consistent with the absence of any mediating effects of change in these measures on intervention effects on the objective primary outcome of MVPA.

# Chapter 5 Economic evaluation

## Introduction

This chapter reports the economic analysis of an augmented ERS with web-based behavioural support (e-coachER) versus ERS alone. Comparing the costs and consequences of alternative approaches to promoting health care is key to facilitating efficient allocation of resources.<sup>66</sup>

Although economic evidence on ERSs exists (mostly compared with usual care), it is unclear;<sup>17</sup> little is known about the value for money of an augmented ERS with online behavioural support. A review of other reviews ( $n = 3$ ) conducted by Pavey *et al.*<sup>54</sup> found one study<sup>67</sup> showing ERSs to be cost-effective, another one<sup>68</sup> reporting mixed findings and a third<sup>69</sup> that found limited evidence of effectiveness but higher cost. In an analysis of 21 economic evaluation studies published by NICE from 2006 to 2010, Owen *et al.*<sup>70</sup> found ERSs to be cost-effective at the NICE threshold of £20,000 to £30,000 per QALY. In a systematic review of economic evaluations, Vijay *et al.*<sup>71</sup> reported three studies showing a cost per disability-adjusted life-year (DALY)/QALY estimate below £10,000 for exercise prescriptions.

The most recent NICE guideline development on ERSs identified two key gaps in knowledge.<sup>72</sup> First, there is paucity of cost-effectiveness evidence on alternative models of ERS. Second, information on the cost-effectiveness of ERSs for people with comorbidities is lacking. We are aware of an ongoing multicountry, multicentre RCT examining the cost-effectiveness of enhanced ERSs plus self-management strategies compared with ERS alone among inactive patients.<sup>73</sup>

This chapter addresses the gaps in the literature by estimating the cost-effectiveness of e-coachER compared with ERSs alone, in adults with range of chronic conditions. The analysis uses a 1-year time horizon (from baseline to 12 months post randomisation) and is conducted from the viewpoint of the NHS, Personal Social Services and patients. The base-case analysis covered NHS and Personal Social Services perspectives.

## Methods

The intervention and control population are as defined in *Chapter 2*. In line with the clinical effectiveness analysis, the samples for base-case analyses are participants who provided valid accelerometry data. Sensitivity analysis explored the impact of using the whole sample.

## Measurement and valuation of cost

Total costs were expressed per participant and calculated by multiplying resource use with each relevant unit cost and summing across the range of resource use possibilities across the 12 months of the study.

Resource use, including those 'in kind', associated with both intervention and control was identified through discussions with the management team of the trial. Following this, resources were measured and valued without research-driven resource use. The range of resource use covered (1) set-up and design of the intervention, (2) delivery of the intervention including handbooks, pedometers, guide for using the LifeGuide platform, technical support and maintenance of the website, (3) consultation provided by an exercise specialist and staff support to participants, (4) primary and secondary health service use: GP, nurse, social worker, care worker, physiotherapist consultations (both home and

practice visits), prescriptions, hospital admissions, accident and emergency (A&E) visits, and other (e.g. podiatrist visits); and (5) time and money expenses borne by participants in relation to participation in the intervention (e.g. time spent on web platform), visit to exercise specialist and PA (e.g. membership fees for gym or sports club). Data on resource use were collected using the trial administrative records, key informant interviews (e.g. trial manager), review of trial management records and participants' questionnaires at baseline, 4 and 12 months.

Resources were valued using national tariffs (e.g. *Unit Costs of Health and Social Care 2017*,<sup>74</sup> *NHS Reference Costs 2015 to 2016*,<sup>75</sup> *Annual Survey of Hours and Earnings*<sup>76</sup>) to increase generalisability. In the absence of available national costs, unit costs came from trial administrative records. *Appendix 6* provides details of unit costs. The unit cost of capital costs (i.e. pedometer) was calculated pro rata (costs were spread over their expected lifetime) because use can occur beyond the time period of this analysis.<sup>77</sup> Costs were expressed in 2017/18 Great British pounds, using the Hospital and Community Health Service (HCHS) inflation index where appropriate (PSSRU 2017).<sup>74</sup> No discounting was used as the time horizon of the analysis is 1 year.

## Measurement and valuation of outcomes

Two types of outcomes were used for estimating cost-effectiveness: physical units (PA indicator) and QALYs. The PA measure is the primary outcome measure of the trial (as described in *Chapter 2*): total weekly minutes of MVPA in  $\geq 10$ -minute bouts, recorded objectively by accelerometer. QALYs were estimated by converting EQ-5D-5L utilities using the area under the curve method. EQ-5D-5L questionnaires were completed by trial participants at baseline and 4 and 12 months. In line with the 2018 NICE recommendation,<sup>66</sup> utility weight based on the crosswalk function<sup>78</sup> was used to assign utility weights. Sensitivity analysis explored the impact of using other valuation sets.

## Methods of analysis

### Missing data analysis

Multiple imputation was employed to replace missing values as it incorporates uncertainty around imputed estimates. Imputed values are drawn from a regression model fitted for each variable with missing data. Multiple imputation by chained equations was used and not multivariate normal imputation as the variables with missing data include binary and categorical variables and these are not suitable with the multivariate normal imputation.

Five imputations were used.<sup>79</sup> The standard approach was followed in building the imputation model as we ensured that the imputation model matched the model used for the analysis while including the predictors of missingness as possible. In addition, the dependent variable was included in the imputation model to ensure that the imputed values have the same relationship to the dependent variable as the observed values.<sup>80</sup>

As the purpose of the multiple imputations was to replace missing values for raw data to allow the generation of derived variables, a point estimate was required, not its variance per se. In line with Rubin's rules,<sup>81</sup> we derived the overall point estimate for the imputations by averaging the estimates of the multiply imputed data. For categorical data, the overall point estimate was rounded up to the nearest decimal point as relevant. The mean of multiple imputations is an unbiased estimate of the missing value, and their contributions to increased variance in subsequent analysis viewed as an estimate of the added uncertainty caused by data missingness.<sup>81</sup>

## Incremental analyses

The within-trial analyses were twofold:

1. Incremental cost-utility analysis – this was the primary analysis of the economic evaluation and used QALY as the effectiveness measure. The outcome of the analysis was cost per QALY.
2. Incremental cost-effectiveness analysis – analysis generated cost per change in MVPA minutes based on accelerometer data indicated in *Chapter 3*.

Descriptive statistics based on mean and SD were conducted for the cost components and quality-of-life measure. Estimations of the outcomes used regression models fitted separately for costs, QALYs and MVPA minutes. Details of the estimation of MVPA minutes is presented in *Chapter 2*. Generalised linear models fitted with gamma and binomial 1 (equivalent to beta regression) distributional families were fitted for the costs and QALYs analyses, respectively.<sup>82,83</sup> The modified Park test was used to select the appropriate distributional family.<sup>82</sup> Regression models adjusted for covariates, as recommended, including baseline QALYs (as appropriate) and potential correlates of the dependent variables age, gender, ethnicity and health condition. Model specification was tested using the link test. All analyses accounted for cluster effect (based on site) through clustered standard errors. Sample means and incremental values for costs and QALYs were estimated using the margins method<sup>82</sup> to improve the precision of estimates. The estimation of standard error and CIs also accounted for the cluster design.<sup>84</sup>

Uncertainty in estimations was analysed using deterministic analyses to examine the impact of (1) using the whole sample (all randomised people) for analysis, (2) changing perspective of analysis to include costs incurred by participants, (3) excluding costs of health and social service use, (4) using different value sets<sup>85</sup> to estimate quality of life and (5) complete-case analysis (excluding missing data). In addition, subgroup analyses were conducted to explore whether or not the cost-effectiveness of the intervention differed across different types of disease groups reported as the reason for referral to the ERS (hypertension, low mood, type 2 diabetes, weight loss and osteoarthritis).

Probabilistic uncertainty was assessed through non-parametric bootstrapping ( $n = 2000$  replications). To ensure that the observations within the resampled clusters are independent in each bootstrap replication, the bootstrap estimation was fitted with unique identifiers inter and intra clusters.<sup>61</sup> Based on the bootstrap samples, cost-effectiveness planes (CEPs) and cost-effectiveness acceptability curves (CEACs) were constructed using the *bsceaprops* program code.<sup>82</sup>

## Results

Summary statistics (unadjusted for baseline differences) on costs to both providers and participants, and quality of life are provided in *Table 23* (see *Appendices 7–9*). At 12 months, the cost to providers per participant was higher in the intervention group (£1730) than in the control group (£1385). The biggest component of the cost borne by providers was health and social service use cost (91%) and the least was cost associated with the provision of support to participants (< 1%, £0.60 per participant). In terms of cost to participants, the pattern was different as participants in the control group incurred an average cost of £298, compared with £255 in the intervention group. The vast majority of this cost was because of cost related to participation in PA (69%). Fees paid for child/dependant care during the exercise specialist visit were the smallest part (< 1%, £0.20 per participant). The intervention group experienced higher quality of life at 12 months with a QALY of 0.662 (*Table 23*).

TABLE 23 Descriptive statistics of costs (2017/18) and quality of life per participant (with accelerometry data)

Costs and quality of life	Mean (SD)	
	Control (n = 133)	Intervention (n = 110)
<b>Cost to providers at 12 months (£)</b>		
Total costs to providers	1385 (2177)	1730 (1707)
Set-up cost	0	182 (0)
Delivery cost	0	29 (0)
Cost of participants' consultation with exercise specialist	30 (45)	29 (45)
Cost of attendance at ERS centre	3.1 (4)	2.5 (3)
Number of ERS attendances <sup>a</sup>	11 (12)	7 (9)
Cost associated with general support to participants	0.3 (1)	1 (2)
Costs of health and social service use	1352 (2180)	1487 (1691)
<b>Cost to participants at 12 months (£)</b>		
Total costs to participants	298 (1252)	255 (347)
Travel cost to visit the exercise specialist	13 (23)	14 (29)
Time cost in consultation with exercise specialist	43 (64)	42 (66)
Fees paid for child/dependant care during exercise specialist visit	0.3 (2)	0.1 (1)
Other expenses related to exercise specialist visit	2 (8)	4 (20)
Time cost using the e-coachER web platform	0	10 (12)
Cost of attendance to ERS centre	27 (34)	18 (26)
Costs related to PA participation	213 (1253)	168 (311)
<b>Quality of life</b>		
QALY (1 year)	0.637 (0.245)	0.662 (0.261)
EQ-5D-5L index (baseline)	0.656 (0.240)	0.663 (0.261)
EQ-5D-5L index (4 months)	0.642 (0.257)	0.672 (0.279)
EQ-5D-5L index (12 months)	0.620 (0.286)	0.641 (0.305)
a Mean imputed attendance rates (over the period of an ERS) varied across the different sites, from 15 in Plymouth to 7 in Birmingham and 3 in Glasgow. Numbers reflect different schemes (see description of schemes elsewhere in the report) and challenges in capturing data, rather than participant interest and success of schemes.		

Table 24 shows the main results based on regression estimates that adjusted for baseline differences. Consistent with the pattern observed in the unadjusted estimates, the average cost per participant was £1355 (95% CI £701 to £2008) and £1793 (95% CI £1635 to £1952) in the control and intervention groups respectively. This represents an additional cost of £439 (95% CI –£182 to £1060) in the intervention group, although the difference is not statistically significant. The intervention led to a weak indicative effect on total weekly minutes of MVPA in bouts of  $\geq 10$  minutes (mean difference 11.8 minutes, 95% CI –2.1 to 26.0 minutes), compared with the control group. In terms of quality-of-life outcome, the intervention group (mean 0.663, 95% CI 0.625 to 0.701) had more QALYs than the control group (mean 0.637, 95% CI 0.585 to 0.688) (see Table 24). The difference in QALYs (0.026, 95% CI 0.013 to 0.040) between the two groups was statistically significant. The cost-utility ratio shows that, compared with the control group, the intervention cost an additional £16,885 per QALY. This is below the NICE threshold of £20,000–30,000 per QALY.

Table 25 shows the results of the deterministic sensitivity analyses. The base-case finding was robust to deterministic sensitivity analyses with a few exceptions. The intervention was found to be more

TABLE 24 Costs, effects and cost-effectiveness at 12 months

Costs and effects	Control		Intervention	
	Mean	95% CI	Mean	95% CI
<b>Within-trial analysis, costs and effects over 12 months</b>				
Total cost per participant (£)	1355	701 to 2008	1793	1635 to 1952
Incremental cost (£)	–		439	–182 to 1060
Total QALYs per participant	0.637	0.585 to 0.688	0.663	0.625 to 0.701
Incremental QALYs	–		0.026	0.013 to 0.040
Incremental total weekly minutes of MVPA in bouts of $\geq 10$ minutes	–		11.8	–2.1 to 26
<b>Within-trial analysis, incremental cost-effectiveness ratio/utility ratio at 12 months</b>				
Cost per additional QALY (£)	–		16,885	
Cost per additional minute of MVPA in a bout of $\geq 10$ minutes (£)	–		37.20	
For incremental analyses, the comparison is intervention vs. control.				

TABLE 25 Sensitivity analyses

Parameter	Incremental cost (£)		Incremental QALY		ICER (£)
	Mean	95% CI	Mean	95% CI	
Base case	439	124 to 754	0.026	0.013 to 0.040	16,885
Whole sample (all participants who were randomised)	439	124 to 754	0.010	–0.005 to 0.024	43,900
Changing cost perspective (both participants and NHS and PSS costs)	413	–266 to 1093	0.026	0.013 to 0.040	15,885
Excluding all health and social care use cost (cost directly related to intervention)	234	216 to 251	0.026	0.013 to 0.040	9000
Complete-case analysis (exclude missing data)	529	–166 to 1223	0.035	0.010 to 0.059	15,114
Changing the values for measuring QALYs (based on EQ-5D-5L value set from Devlin <i>et al.</i> <sup>85</sup> )	439	–182 to 1060	0.030	0.022 to 0.039	14,633
Participants with hypertension ( $n = 37$ )	–46	–1260 to 1168	0.009	–0.020 to 0.038	Intervention dominates control
Participants with low mood ( $n = 84$ )	989	637 to 1341	–0.056	–0.098 to –0.014	Control dominates intervention (less expensive and more effective)
People with type 2 diabetes ( $n = 49$ )	655	–187 to 1497	0.044	–0.021 to 0.110	14,886
Participants who were overweight ( $n = 227$ )	350	–44 to 745	0.019	–0.035 to 0.072	18,421
Participants with osteoarthritis ( $n = 53$ )	223	–781 to 1228	0.018	–0.016 to 0.052	12,389
PSS, Personal Social Services.					

expensive but produced more QALYs. Excluding health and social service use costs, or changing the perspective of analysis, improved the cost-effectiveness of e-coachER, with incremental cost-effectiveness ratios (ICERs) ranging between £9000 and £15,885. Using estimates based on the whole sample (all participants who were randomised) was decisionally significant. It produced a worse cost-effectiveness ratio, with the intervention becoming not cost-effective (£43,900 per QALY).

Compared with the base-case findings, subgroup analysis showed the intervention to be more cost-effective in groups that reported that hypertension (dominates control) or osteoarthritis (ICER £12,389 per QALY) or type 2 diabetes (ICER £14,886 per QALY) was the primary reason for referral. Among individuals who reported that being overweight was the primary reason for referral, e-coachER was still cost-effective but at a higher ICER value (£18,421 per QALY). In the group that reported that low mood was the primary reason for referral, e-coachER was more expensive (additional cost of £989 per participant) and less beneficial (fewer QALYs of -0.056 per participant) than the control.

Figure 7 shows the cost-effectiveness plane for the intervention compared with the control. The majority of the cloud of points (representing mean differences in costs and QALYs) are located in the north-east quadrant of the plane. This indicates that the intervention has high likelihood of generating more QALYs but at higher costs. The probability of the intervention being cost-effective (compared with control) at multiple willingness to pay per QALY values is presented in Figure 8. At £10,000 per QALY, the intervention has about 30% chance of being cost-effective compared with the control. The likelihood of cost-effectiveness nearly doubles (51%) at the £20,000-per-QALY threshold and increases further to 63% at the £30,000 threshold.

## Discussion

This study shows that providing online behavioural support for participants of ERSs cost providers £1793 per person. Although the intervention costs £439 more than offering the ERS alone, it leads to better quality-of-life outcomes (0.026 more QALYs per person) and increased participation in PA (12 more weekly minutes of MVPA in  $\geq 10$ -minute bouts per person). Although the differences were mostly not statistically significant, it is important to note that this is not sufficient proof of no significant effect, as the clinical trial was not powered to identify the changes in the economic

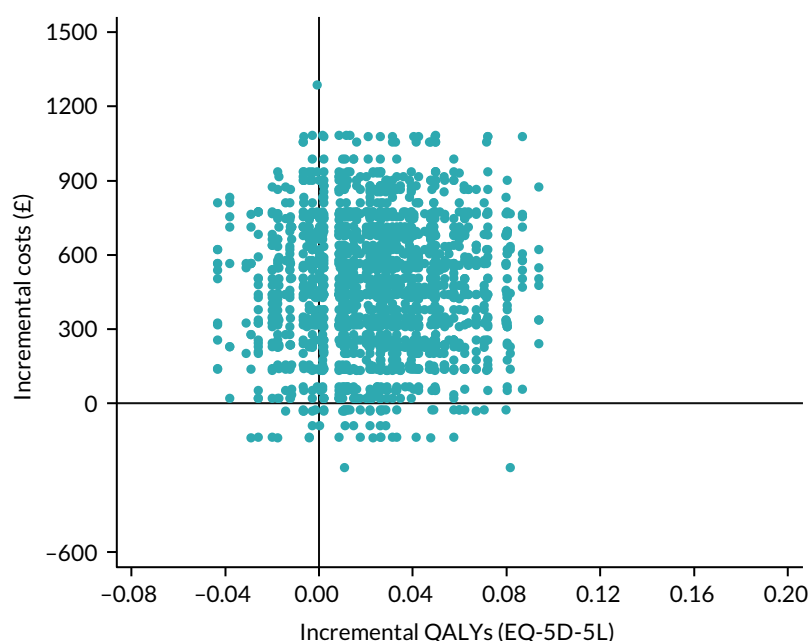
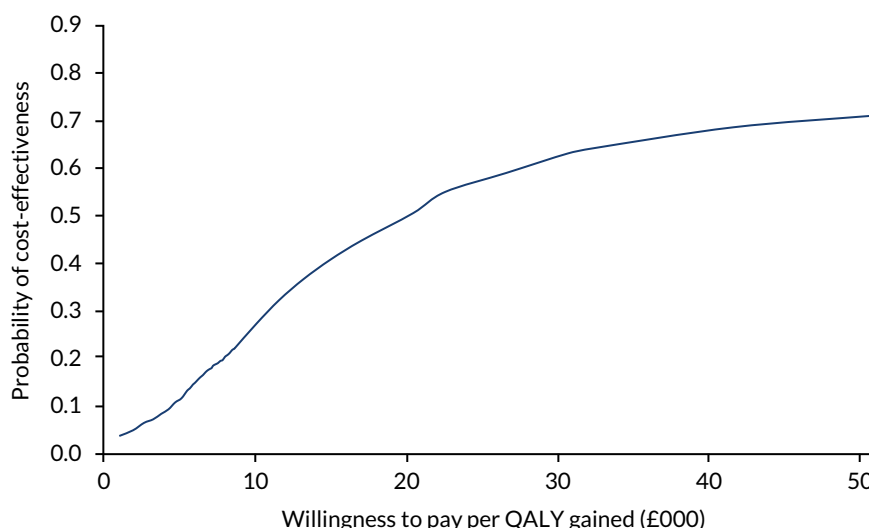


FIGURE 7 Cost-effectiveness plane for intervention vs. control at 12 months.





**FIGURE 8** Cost-effectiveness acceptability curve showing the probability of within-trial cost-effectiveness for intervention vs. control at different willingness to pay per QALY thresholds.

outcomes (cost and QALY), particularly given the small number of observations in the subgroup analysis. Compared with the control, the intervention cost an additional £37 to gain a 1-minute increase in weekly MVPA (in  $\geq 10$ -minute bouts) and £16,885 per QALY gain per person. Based on the NICE threshold of £20,000–30,000 per QALY, e-coachER could be considered more cost-effective than ERS alone. If decision-makers are willing to pay £30,000 for 1 QALY, e-coachER has a 63% probability of being cost-effective. The findings were robust to sensitivity analysis, including when the cost of participants was added to total costs of the programmes. Exploratory subgroup analysis found that the intervention was cost-effective among participants who reported that hypertension, osteoarthritis, type 2 diabetes or weight problems (i.e. being overweight) was the primary reason for referral but was not cost-effective among those who reported that low mood was the primary reason.

The novelty of e-coachER, its comparison with usual ERSs and the disease-specific population makes it complicated to relate the findings here meaningfully to the existing economic literature on ERSs. We identified one comparable study. Murphy *et al.*,<sup>17</sup> a pragmatic RCT, assessed the cost-effectiveness of the Wales National Exercise Referral Scheme (NERS), a 16-week programme including motivational interviewing, goal-setting and relapse prevention compared with usual care. Participants were inactive people with depression and/or coronary heart disease risk. The NERS intervention was shown to be cost-effective at 12 months, with a cost-per-QALY estimate of £12,111 and 89% likelihood at the £30,000-per-QALY threshold.

Our analysis found that costs associated with health and social services constitute the largest proportion of total costs associated with the intervention. Although the impact on cost-effectiveness was not decisionally insignificant, an important consideration is why the intervention group had higher health service use cost (mean cost of £135) than the control group. Further exploration shows that in the first 4 months of the trial, on average, the intervention group had a health service cost of £819 per participant and the control group had a health service cost of £639 per participant (see *Appendix 9*). In terms of the subcomponents of health service use cost collected in this study ( $n = 13$ ), the intervention had higher costs in all except two [A&E visits and hospital visits (outpatients)]. The reverse pattern was, however, observed from 5 to 12 months – the control group had higher health service costs than the intervention group (£713 vs. £668). Similarly, the control group had higher costs for all subcost components apart from prescriptions and care worker visits. A systematic review on injury consequences of PA found that, although relatively minor, increased activity could lead to adverse health consequences.<sup>86</sup> However, for older adults, improved participation reduces the risk of fall-related injuries.<sup>87</sup> Future studies are required to further investigate the impact of adverse effects on the cost-effectiveness of PA programmes.



This study feeds into a limited evidence base around the efficiency of different models of ERS. To the best of our knowledge, this is the first study to demonstrate the cost-effectiveness of online support for an ERS and in a population with common chronic conditions. The strengths of this study include the use of robust clinical effectiveness data from a large multicentre trial, rigorous analyses to determine the impact variant measures of quality of life and participant perspective, subgroup analysis among different disease groups, comprehensive coverage of health service and social care use cost. A key limitation, however, is the short-term perspective of the analysis herein. Modelling of the long-term costs and effects is important where benefits and costs extend beyond the end of a trial. It is of particular relevance to this trial, where the benefits or costs could be experienced in the future too (as resource savings from reduced disease and, therefore, benefits in terms of increased quality of life). We expect that the impact of the long-term effects may have underestimated the cost-effectiveness of e-coachER.

There is currently limited national public health guidance on the implementation of ERSs enhanced with online support for participants. The results herein show that based on the NICE threshold of £20,000–30,000 per QALY, e-coachER could be considered more cost-effective than ERS alone. To strengthen the economic case, future studies are recommended to examine the long-term cost-effectiveness of the e-coachER and ascertain the impact of the trajectory of activity levels on future health service and future quality of life.

# Chapter 6 Discussion

## Summary of findings

The 450 trial participants were 64% female ( $n = 290$ ), had an average age of 50 years and had an average BMI of 32.6 kg/m<sup>2</sup>; 65% and 35% were classified as inactive ( $n = 293$ ) and moderately inactive ( $n = 157$ ), respectively, and 50% reported that weight loss was the primary reason for referral ( $n = 225$ ), followed by low mood ( $n = 85$ , 19%), osteoarthritis ( $n = 54$ , 12%), diabetes or prediabetes ( $n = 49$ , 11%) and high blood pressure ( $n = 36$ , 8%). Participants also noted that weight loss ( $n = 364$ , 81%), low mood ( $n = 243$ , 54%), high blood pressure ( $n = 149$ , 33%), diabetes or prediabetes ( $n = 117$ , 26%) and osteoarthritis ( $n = 108$ , 24%) may have been one of the reasons for referral.

The e-coachER support package was developed, which included mailing participants a pedometer, a fridge magnet with attached tear-off strips to record daily PA and a bespoke website to overcome barriers to increase daily PA for some people who are not willing or able to engage in an ERS. The e-coachER intervention demonstrated a mixed level of engagement. About one-third of participants did not register online and about one-third completed what we thought would be an adequate 'dose' of at least five of the seven steps, involving at least setting a PA goal and reviewing it 1 week later.

The results show that, compared with usual ERSs, the e-coachER intervention group had slightly more, but not significantly more, accelerometer-recorded minutes of MVPA (recorded in bouts of  $\geq 10$  minutes) at 12 months. The pattern was similar when considering the level of intervention engagement, with a slightly larger difference in favour of the intervention group. Applying the same approach as in the primary analysis, there were no between-group differences at 12 months in any of the other accelerometer-derived or self-reported MVPA outcomes, with one exception. The intervention group had significantly more daytime sedentary time (accumulated in blocks of  $\geq 5$  minutes) at 12 months. In ITT imputed comparison at 12 months, the intervention group was more likely than the control group to self-report that they had achieved 150 minutes of weekly MVPA (odds ratio 1.55, 95% CI 0.99 to 2.42;  $p = 0.05$ ). The intervention also had no effect on ERS attendance (78% vs. 75% in control and intervention, respectively), or EQ-5D-5L or HADS scores at 12 months, compared with the control group. In ITT imputed comparison at 12 months, the intervention group had lower HADS depression and anxiety scores than the control group. The proportion of participants attending the ERS was comparable to findings from a review<sup>15</sup> that reported that the average ERS uptake was 81% in RCTs.

## Economic evaluation

Over the 12-month follow-up, the average cost per participant was £1355 (95% CI £701 to £2008) and £1793 (95% CI £1635 to £1952) in the control and intervention groups respectively. Compared with the control group, the intervention group incurred an additional mean cost of £439 (95% CI –£182 to £1060) but generated more mean QALYs (0.026, 95% CI 0.013 to 0.040), with an incremental cost-effectiveness ratio of an additional £16,885 per QALY.

Although insignificant, an important consideration is why the intervention group had higher health service use cost (mean cost of £135) than the control group given the intervention was effective and led to increases in both PA and health-related quality of life. The difference in the cost, which was not statistically significant, was observed irrespective of the central measure of tendency, mean or median (see *Appendix 9*). Further exploration shows that in the 4 months of the trial, on average, the intervention group had a health service cost of £819 and the control group had a cost of £639. In terms of the subcomponents of health service use cost collected in this study ( $n = 13$ ), the intervention

group had higher costs in all except two components [A&E visits and hospital visits (outpatients)]. The reverse pattern was, however, observed from 5 to 12 months, with the control group qualitatively having greater health service costs (£713 vs. £668). Similarly, the control group had higher costs for all subcost components apart from prescriptions and care worker visits.

## Effectiveness of and engagement in the intervention

One of the criticisms of e- and m-health interventions is that engagement is not appealing to enough people and can be rather short-lived.<sup>23</sup> The 9-month work in developing the intervention, building on other effective LifeGuide interventions and with public and patient involvement, aimed to maximise engagement to theoretically have the greatest impact on MVPA outcomes at 12-month follow-up. Automated periodic e-mails were sent to intervention participants up to 12 months. The intervention included evidence-based and theory-driven components as well as a pragmatic approach to enhance engagement. Pedometers and recording sheets attached to fridge magnets were provided in the initial introductory pack as basic tools for self-monitoring PA and setting and reviewing SMART goals. These may have been sufficient to get some of the 36% of intervention participants who never registered to think about behavioural self-regulatory processes to increase PA for managing their chronic condition (s). Attending the ERS may also have provided sufficient support to become more physically active, without the use of the pedometer or web-based support. Other participants may also have regarded the pedometer as rather basic and decided to use a more sophisticated app on their smartphone.

The fact that 64% of participants did register online and completed their first step, with 36% going on for over 4 weeks to complete a goal review, provided us with some assurance that the e-coachER intervention was acceptable for a reasonable proportion of participants. There is evidence from previous research with LifeGuide interventions that even limited online engagement can be effective and there is no clear 'adequate dose' to optimise behavioural change. Our CACE analysis confirmed that completing our prespecified intervention engagement level (step 5) did not lead to significantly greater 12-month objectively recorded minutes of MVPA, recorded in  $\geq 10$ -minute bouts, compared with the control group, although the between-group differences were qualitatively greater (22.9 vs. 11.8 minutes).

Our logic model predicted that e-coachER engagement would strengthen various beliefs that would in turn translate into increases in MVPA, compared with usual ERS support. Among only the participants included in the primary analysis, the intervention did increase the following compared with the control group: perceived importance of doing at least 30 minutes of moderate-intensity PA (e.g. brisk walk) on at least 5 days per week, confidence in achieving at least 30 minutes of moderate-intensity PA (e.g. brisk walk) on at least 5 days per week and perceived competence in being regularly physically active at 4 months (but not 12 months). Changes (from baseline to 4 months) in these process outcomes did not mediate changes in the primary outcome at 12 months.

In the qualitative part of our process evaluation, 12% of intervention participants were interviewed. Overall, e-coachER was acceptable and positively experienced and did 'do what it said on the tin' in terms of enhancing autonomy, competence and relatedness for many participants. Inevitably, because the web-based support was available to support participants with a range of levels of IT literacy and chronic conditions, some of the content did not appeal to everyone. That said, the idea that the support aimed to facilitate engagement with the self-monitoring process and then encourage them to move on to using more sophisticated devices to self-monitor PA for example, was overlooked by some participants, but not all. Similarly, we tried to help participants to find any source of social support to support increases in PA and a preferred form of PA that they could enjoy, whether or not that involved the ERS, and that overarching intent 'may have been lost' by some of those interviewed. The user guide sent to intervention participants initially could have spelled out some aims of the support more explicitly and if this had been understood then some comments from participant interviews may not have been made. That said, some

interviewees did note that they had a strong IT background and acknowledged that their comments were personal and acknowledged the need to appeal to those with a lower level of IT literacy than themselves.

## Strengths and limitations

### *Sample characteristics*

We believe this to be the first study to recruit inactive participants with chronic conditions into a trial involving ERSs, and then follow them up at 12 months to assess objectively measured PA. We had planned to conduct separate analyses for different chronic conditions to explore the possibility of establishing an evidence-based case for disease-specific ERS pathways, but the study findings have clearly confirmed the extent of multimorbidity. Nevertheless, when considering the participant-reported primary reason for referral, in sensitivity analysis there was no interaction between this reason and the overall intervention effects on the 12-month MVPA primary outcome.

During the course of the study, we recalculated the sample size to recruit 430 participants (decreased from original funding application sample size of 900), allowing for 20% attrition for the primary outcome at 12 months. We actually recruited 450 participants, but, partly because we set a very rigorous primary outcome threshold (wear-time of at least 4 days per week, including 1 weekend day, with data from at least 16 hours per day), the primary analysis was based on data from 232 participants. Further analysis explored if more lenient thresholds, which resulted in more participants being involved in the analysis, influenced the findings. The overall findings remained consistent.

### *Exercise referral scheme context*

The e-coachER intervention was designed with considerable public and patient input to ensure that it would support patients with a wide range of IT expertise. We categorised 16% of trial participants as having low IT literacy and further analysis revealed that IT literacy did not have an impact on the primary analysis.

Exercise referral schemes are delivered in various formats across the UK and we were keen to ensure that the trial produced findings with good generalisability. In other words, we wanted to know if adding the e-coachER intervention improves long-term levels of MVPA in patients with chronic conditions. The three sites in which recruitment took place offered quite different types of ERS, which have been described elsewhere.<sup>1</sup> For example, in Glasgow the ERS involves initial contact with an ERS practitioner, who provides some behavioural support to increase MVPA and also helps to signpost participants to preferred and appropriate PA opportunities, with following consultations available at 6 and 12 months. In contrast, the schemes in Birmingham and the South West are more traditional ERSs with support provided by an ERS professional in an exercise facility. Within the trial, we examined the impact of site on the primary analysis and found no different effects of the intervention across sites.

A further strength of the study was the use of an evidence-based, theory-driven intervention that allowed us to identify website usage. The LifeGuide system provided data on number of visits (and duration) to the website and which steps were completed. Our detailed mixed-methods process evaluation allowed us to collate this information and explore the impact of engagement on cognitive and behaviour processes we had proposed within our logic model. In turn, we were able to explore if changes in these process outcomes mediated changes in the primary outcome.

### *Accelerometer measures at 12 months*

To our knowledge, this is the first trial of an ERS to objectively assess MVPA at follow-up. Only one previous trial has involved a 12-month follow-up to assess the long-term effects of an ERS intervention on PA and that was based on self-reported measures. Owing to the very low levels of MVPA in the present sample, relative to other studies, new challenges have appeared for data analysis. We prespecified our

primary outcome and the research team, TSC and DMC have been involved in discussions about the most appropriate approach to data analysis. The statistical analysis plan was agreed and signed before seeing the data. In our primary analysis, we present various scenarios from extensive exploratory modelling, and also sensitivity analysis using different thresholds for analysing raw accelerometer data. These analyses, and those of the self-reported MVPA data, will provide valuable insights into how best to examine within-trial PA data. At the time of writing, we understand that national and international guidelines for completing MVPA weekly minutes are expected to no longer mention the need to accumulate MVPA in at least 10-minute bouts. Our analyses provide a broad range of findings that will contribute to the understanding of past and future evidence and research.

The accelerometer findings were broadly similar to self-report measures in terms of between-group differences, but levels of activity were strongly influenced by the way the data were collected and processed. Only participants classified as inactive or moderately inactive according to the GPPAQ were included in the study but, at baseline, self-reported data revealed that 36% met the 150 minutes per week MVPA guideline, and accelerometer data revealed that 80% met the guideline from non-bouted activity and only 4% met it from activity recorded in bouts of  $\geq 10$  minutes. Others have also shown lower levels of accelerometer-recorded MVPA minutes when data are processed using  $\geq 10$ -minute bouts compared with bouts of at least 1 minute.<sup>55</sup> Current national and international guidelines do not fully reflect this variability because of measurement method.

Given the overdispersion and high frequency of zero counts, the primary statistical model was found to poorly fit and post hoc analysis models were therefore also explored. For example, for the primary outcome of total weekly minutes of MVPA in  $\geq 10$ -minute bouts, 142 out of 243 (58%) participants at 12 months had zero scores and the SD (60.0) was more than two times the mean value (26.2). It is important to recognise the limitations of all these models. These include lack of fit of the models and the need to assume data as counts for some models. However, reassuringly, the interpretation of the impact of the intervention on primary outcome analysis was insensitive to the choice of statistical model.

Although the effectiveness findings show only a weak indicative effect on MVPA at 12-month follow-up, these changes were found to have a 63% probability of being cost-effective based on a UK threshold of £30,000 per QALY.

The mixed-methods process evaluation indicated that the intervention was generally acceptable and of value to patients with a variety of physical and mental health conditions. The intervention resulted in changes in some but not all behaviour change processes that we designed the intervention to change. Notably, the perception of importance of being physically active was greater as a result of the intervention compared with the control group, at both 4 and 12 months. Step 1 in the intervention involved a quiz about the benefits of PA for health generally and also specific chronic conditions. In other steps, we encouraged participants to feel the broader value of being active for both physical and mental well-being. By supporting change in MVPA it is likely that intervention participants learned to place greater value and importance on being physically active, but improvements in confidence to be physically active and a perception of importance of being more physically active did not mediate any effects of the intervention on MVPA at 12 months.

## Implications for health care

Offering e-coachER support had only small but non-significant effects on objectively recorded MVPA compared with usual ERSs at 12 months. The cost-utility ratio shows that when compared with the control, the intervention cost an additional £16,885 per QALY and has a 63% probability of being cost-effective for increasing MVPA, compared with usual ERS.

As a result of usual ERS alone (i.e. in the control group), across the sites there was only weak evidence of a change in accelerometer-recorded MVPA at 4 months, but none at 12 months, albeit without comparison with no ERS. If anything, there were small but non-significant reductions in MVPA among only those engaging in usual ERS. The rationale for conducting the present study was that we offered an additional 'package' of support (e-coachER) aimed at developing self-determined PA alongside usual ERSs or instead of usual ERSs. If shown to add additional benefit, our intervention would be available to primary care professionals to offer to inactive patients, with a range of physical and mental health conditions, at the time of making a referral to a local ERS.

Providing web-based behavioural support to participants of ERSs offers an additional strategy to augment usual ERSs to promote PA. There are a few small aspects of the intervention that we would change based on participant feedback, but the intervention could also be extended to be suitable for use by patients with other chronic conditions (e.g. cancer). There was reasonable engagement in e-coachER support for participants with a range of confidence in using IT, indicating that, if implemented, it would have low costs and moderate value in promoting PA in addition to usual ERSs. Our process evaluation indicated that there were changes in some of the measures that we collected to assess key components of the logic model. For example, the intervention led to improvements up to 4 months in confidence and competence in doing PA, perceiving the importance of PA, a sense of availability of support, action-planning and self-monitoring compared with the control group. But these intervention effects were sustained at 12 months only for perceived importance of PA. In our exploration of whether or not any of the changes between 0 and 4 months mediated any intervention effects on the primary outcome (accelerometer-recorded minutes of MVPA in bouts of  $\geq 10$  minutes) at 12 months, there was no evidence that this was the case. Our ability to detect these mediation effects may have been limited by the overall intervention effects on MVPA at 12 months.

The present study found that 36% of participants did not log into the online e-coachER support, but did receive a pedometer and a fridge magnet to record MVPA. We will further analyse the data to determine if this was sufficient to increase MVPA compared with usual ERSs. Other evidence suggests that providing primary care patients with a pedometer to self-monitor PA is effective in changing objectively recorded MVPA.<sup>61</sup> It would be relatively easy to provide patients with a pedometer at the same time as referring them to an ERS.

The LifeGuide platform has been used to deliver evidence-based and theory-driven interventions online to support change in a wide range of health behaviours. One of its strengths is the ability to capture intervention engagement to help understand fidelity issues and add to the literature on how people change as a result of e-health interventions. Although LifeGuide-delivered interventions do these things well and have been shown to be effective in supporting change in a range of health behaviours and weight loss, other more sophisticated technological innovations are rapidly taking over. Indeed, feedback captured within our process evaluation noted that the e-coachER support was rather unsophisticated, and typing step counts or minutes of MVPA accumulated in the past week into a website and getting feedback on whether or not goals had been achieved can instead undoubtedly be done on a range of more sophisticated devices that are embracing digital technology and artificial intelligence. For these reasons, the LifeGuide platform will no longer support digital interventions from 2021.

We hoped that the intervention would encourage participants to go to the local ERS that they had been referred to but this did not happen. Almost 25% of referred participants did not attend any sessions.

## Future research implications

Previous research has compared usual ERSs with an enhanced ERS, involving additional exercise practitioner training, but showed no additional effect<sup>20</sup> on PA. The present trial provides no clear support for adding a web-based support package to usual ERSs, to increase long-term MVPA.



Our process evaluation revealed that some improvements to the web support could be made, such as mobile options with smartphone apps for self-monitoring and goal-setting.

The modest engagement in the online e-coachER support suggests that work is needed to understand which factors influenced intervention engagement and how best to further develop low-cost and scalable support to increase ERS uptake and maintenance of PA. Once this has been done, further research could examine the effects of a modified e-coachER-type intervention for participants with chronic conditions involved in the present study and others (e.g. with cancer, back pain and in cardiac rehabilitation).

The e-coachER study has provided a rich data set, which offers the chance to explore additional questions including the following:

- What were the characteristics of participants that predicted changes in 4- and 12-month PA?
- How did different measures of MVPA (i.e. self-report and accelerometer derived) influence the findings, beyond what we present here?
- What other aspects of intervention engagement (derived from the LifeGuide platform) were used, and did any influence changes in process and behavioural outcomes?
- Among subsets of the sample (e.g. those with low mood), what changes in quality of life, depression and anxiety occurred as a result of the intervention versus usual ERSs?

## Conclusions

With modest engagement in the evidence-based and theory-driven e-coachER intervention, which was captured by the web-based system, the intervention effects on a rigorously defined, objectively assessed, PA primary outcome at 12 months were only small and not significant, and, because of a smaller sample size than intended, should be treated with caution.

In the cost-effectiveness analyses, the cost-utility ratio shows that, compared with an ERS alone, ERS plus the e-coachER intervention cost an additional £16,885 per QALY and has a 63% probability of being cost-effective based on the UK threshold of £30,000 per QALY.

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Professor Sarah Dean developed the process evaluation plan with Dr Jeffrey Lambert, Professor Colin Greaves, **Mr Nigel Charles** (Associate Research Fellow) and **Dr Rohini Terry** (<https://orcid.org/0000-0003-4188-8504>) (Research Fellow). Professor Sarah Dean led the analysis and reporting of the qualitative analysis for the process evaluation, in collaboration with Professor Colin Greaves, Mr Nigel Charles, Dr Rohini Terry and Professor John Campbell (<https://orcid.org/0000-0002-6752-3493>).

Dr Nana Anokye provided the health economics evaluation plan and conducted and reported the economic evaluation in accordance with the health economics evaluation plan.

Professor Rod S Taylor provided the statistical analysis plan and conducted and reported the statistical analysis in accordance with the statistical analysis plan.

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**Mr Chris Cavanagh** was the PPI representative.

All authors critically revised successive drafts of the manuscript and approved the final version.

## Publications

Ingram W, Webb D, Taylor RS, Anokye N, Yardley L, Jolly K, *et al.* Multicentred randomised controlled trial of an augmented exercise referral scheme using web-based behavioural support in individuals with metabolic, musculoskeletal and mental health conditions: protocol for the e-coachER trial. *BMJ Open* 2018;**8**:e022382.

Taylor AH, Taylor RS, Ingram W, Dean S, Jolly K, Mutrie N, *et al.* A randomised controlled trial of an augmented exercise referral scheme using web-based behavioural support for inactive adults with chronic health conditions: the e-coachER trial. *Br J Sports Med* 2020; in press.

## Data-sharing statement

All data requests should be submitted to the corresponding author for consideration. Access to available anonymised data may be granted following review and appropriate agreements being in place.



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## Appendix 1 Illustrative screenshots from the e-coachER website



**e-coachER**  
Web support for exercise referrals

Making Your Step Plans

### Your step goal!

Now you have some information about the benefits of setting small step goals and some tips on how to achieve them, why not try bringing it together and set your own step goal? Your **Exercise Referral Practitioner** may be able to help with this.

On average, people usually walk between 2000 and 4000 steps a day, just in their everyday activities.

The aim is to increase your step count very gradually without needing to make a special effort.

Why not try setting **your own step goal** using the drop down box below?

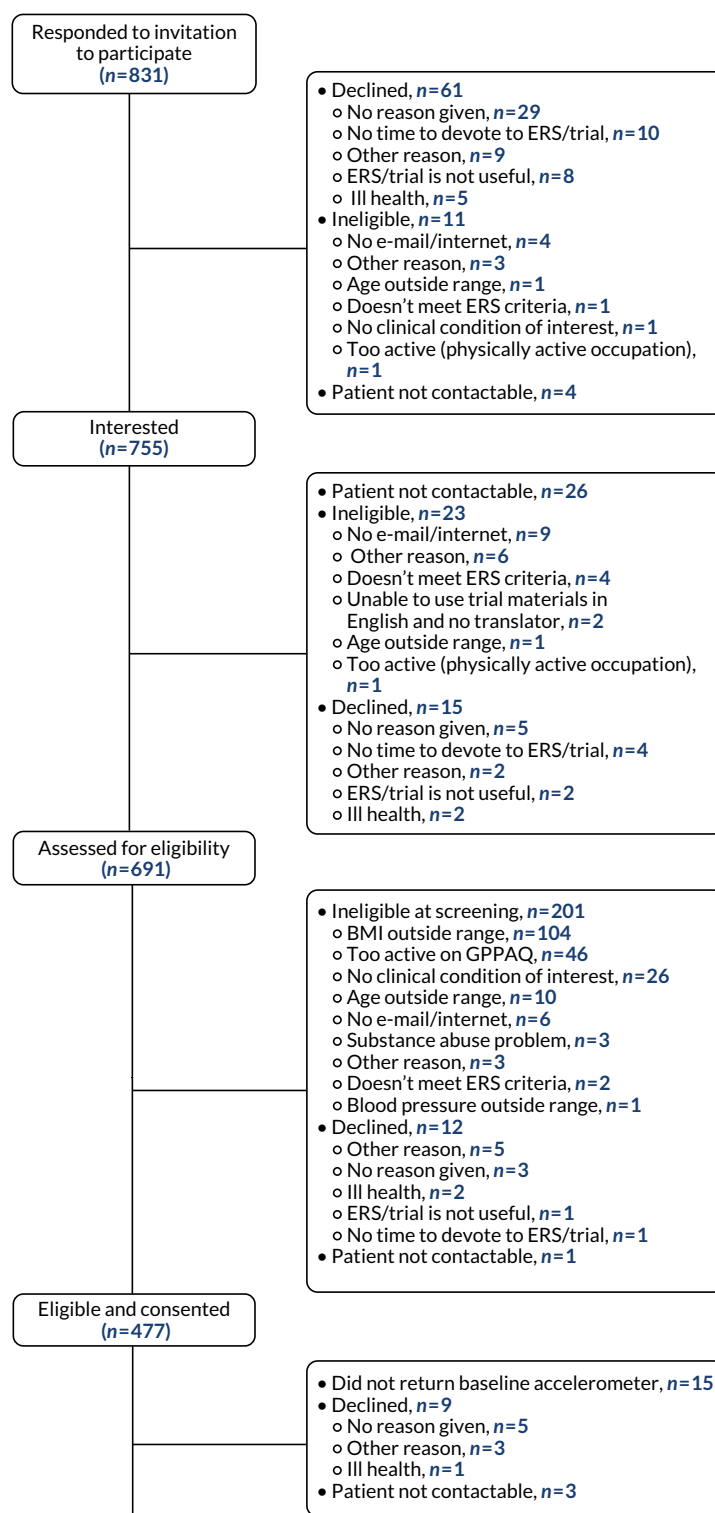
Back

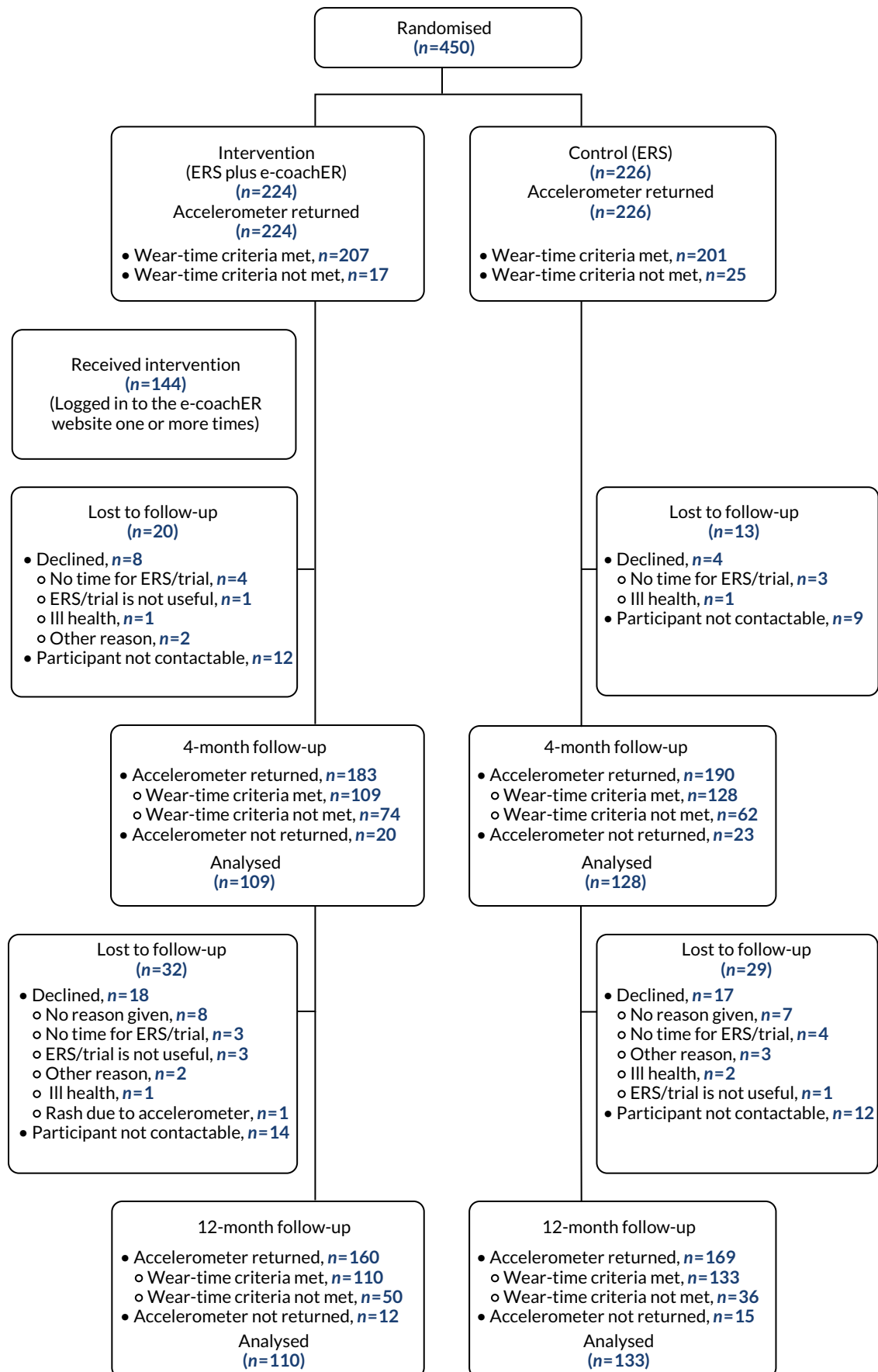
For the next week my goal is to walk  Steps per day

Next

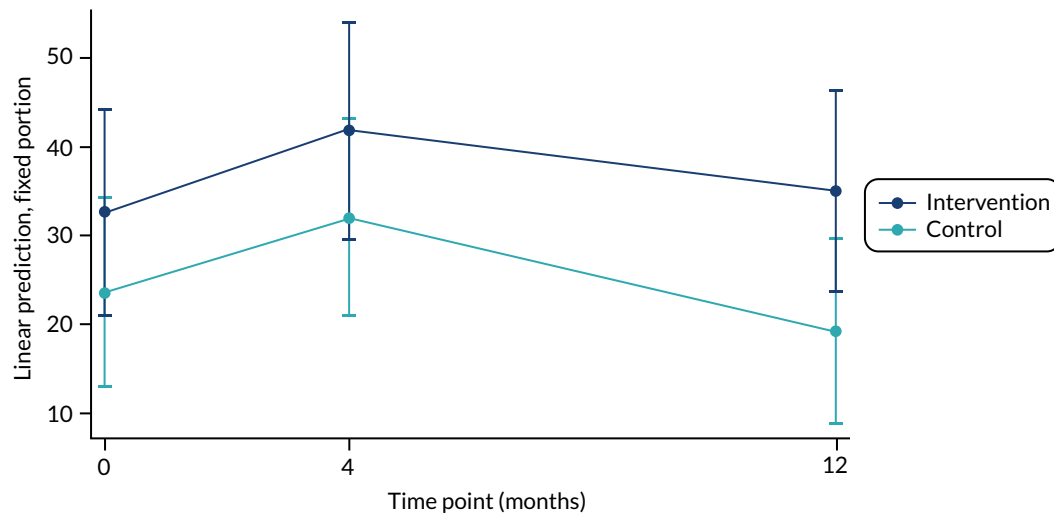


## Appendix 2 The CONSORT flow diagram (detailed)





## Appendix 3 Estimates for repeated-measures model for the primary outcome





## Appendix 4 Serious adverse events

### Serious adverse events reported in the control group

Serious AEs were hospitalisations, with the exception of SAE010029/001 (Morton's neuroma), which was categorised as 'persistent/significant disability/incapacity'.

Site	SAE log number	Outcome	Relationship of the event to the study processes	MedDRA organ system	Summary description of event
03	SAE030003/002	Recovered with sequelae	Not related	Neoplasms (2)	Diagnosed with chronic myeloid leukaemia
03	SAE030210/002	Recovered	Not related	Neoplasms (2)	Prolonged hospitalisation caused by recurrence of breast cancer
03	SAE030184/001	Ongoing	Unlikely	Psychiatric (7)	Inpatient stay on mental health ward
03	SAE030210/001	Recovered	Not related	Psychiatric (7)	Hospitalised for depression
01	SAE010029/001	Ongoing	Not related	Nervous system (8)	Morton's neuroma
01	SAE010081/001	Recovered	Unlikely	Respiratory (13)	Treated in hospital for fluid on the lungs
03	SAE030157/001	Recovered	Not related	Gastrointestinal (14)	Varices of gastrointestinal tract. Prolonged inpatient stay caused by major organ system involvement
02	SAE020261/001	Recovered	Not related	Musculoskeletal (17)	Admitted to hospital because unable to walk
02	SAE020194/001	Recovered	Not related	Pregnancy (19)	Childbirth and postnatal inpatient stay
03	SAE030157/002	Recovered	Not related	Investigations (23)	Admitted to hospital with symptoms of meningitis
02	SAE020193/001	Recovered with sequelae	Not related	Investigations (23)	Collapse. No diagnosis made
01	SAE010007/001	Recovered	Not related	Surgical/medical (25)	Planned admission for femorodistal bypass (peripheral vascular disease), subsequent infection/abscess behind knee
03	SAE030003/001	Recovered	Not related	Surgical/medical (25)	Hospitalised for treatment of boils in groin
01	SAE010139/001	Recovered	Not related	Surgical/medical (25)	Planned hospital admission for bunion removal
01	SAE010139/002	Recovered	Not related	Surgical/medical (25)	Planned hospital admission for bunion removal
03	SAE030065/001	Recovered	Unlikely	Surgical/medical (25)	Hospital admission for treatment for diverticular bleeding
02	SAE020342/001	Recovered	Not related	Surgical/medical (25)	Injury to foot led to planned admission for partial amputation of left great toe
01	SAE010088/001	Recovered	Not related	Surgical/medical (25)	Planned hospital admission for right hip replacement



Site	SAE log number	Outcome	Relationship of the event to the study processes	MedDRA organ system	Summary description of event
03	SAE030171/001	Recovered	Not related	Surgical/medical (25)	Planned hospitalisation for total hip replacement
01	SAE010098/001	Recovered	Not related	Surgical/medical (25)	Planned hospital admission for total knee replacement
02	SAE020111/001	Recovered	Not related	Surgical/medical (25)	Preplanned hospitalisation for knee surgery because of osteoarthritis
02	SAE020195/001	Recovered with sequelae	Not related	Surgical/medical (25)	Planned admission for total right knee replacement
02	SAE020195/002	Recovered with sequelae	Not related	Surgical/medical (25)	Planned admission following infected right knee joint – continuing physiotherapy and using crutches
02	SAE020313/001	Recovered	Not related	Surgical/medical (25)	Hospitalisation for emergency operation on knee following a number of falls and pre-existing weakness in knee
01	SAE010063/001	Recovered	Not related	Surgical/medical (25)	Hospital admission for surgical repair of bulging disc in lower back
02	SAE020185/001	Recovered	Not related	Surgical/medical (25)	Hospitalised because of complications from type 2 diabetes and heart failure

The number of SAEs reported per participant is indicated in the suffix of the SAE log number. Some participants had two SAEs, as indicated by '002' in bold text.

## Serious adverse events reported in the intervention group

Serious AEs were hospitalisations, with the exception of SAE010011/001 (asthma attack), which was categorised as a life-threatening event.

Site	SAE log number	Outcome	Relationship of the event to the study processes	MedDRA organ system	Summary description of event
01	SAE010104/001	Recovered	Not related	Cardiac (11)	Admitted to hospital with abnormal ECG. Diagnosis: paroxysmal atrial fibrillation
03	SAE030240/001	Recovered	Not related	Cardiac (11)	Hospitalised because of a heart attack
03	SAE030134/001	Recovered	Unlikely	Vascular (12)	Hospitalised because of minor stroke
01	SAE010011/001	Recovered	Not related	Respiratory (13)	Asthma attack

Site	SAE log number	Outcome	Relationship of the event to the study processes	MedDRA organ system	Summary description of event
01	SAE010119/001	Recovered	Not related	Investigations (23)	Hospital admission for suspected meningitis. No formal diagnosis made. Symptoms attributed to adverse effects of prescription medication
01	SAE010159/001	Recovered	Not related	Investigations (23)	Fall resulting in fracture of left radius. Admitted for investigations of reasons for the fall
01	SAE010160/ <b>002</b>	Recovered	Not related	Surgical/medical (25)	Admitted to hospital following fall with fracture to right ankle and trauma to right knee
01	SAE010115/ <b>002</b>	Recovered	Not related	Surgical/medical (25)	Preplanned hospital admission for abdominal surgery
03	SAE030078/001	Recovered	Not related	Surgical/medical (25)	Planned hospitalisation for operation on right ankle
02	SAE020290/001	Recovered	Not related	Surgical/medical (25)	Admitted to hospital for 1 day (day case) because of osteoarthritis
01	SAE010201/001	Recovered	Not related	Surgical/medical (25)	Planned hospital admission for tendon surgery on hand related to rheumatoid arthritis
03	SAE030049/001	Recovered	Unlikely	Surgical/medical (25)	Hospital admission for treatment of rheumatoid arthritis flare-up
02	SAE020354/001	Recovered	Not related	Surgical/medical (25)	Inpatient stay for removal of Bartholin's cyst
01	SAE010115/001	Recovered	Not related	Surgical/medical (25)	Planned hospital admission for knee replacement
01	SAE010160/001	Recovered	Not related	Surgical/medical (25)	Planned admission for partial right knee replacement
03	SAE030102/001	Recovered	Not related	Surgical/medical (25)	Hospitalised for surgery on both knees, as treatment for long-standing osteoarthritis

ECG, electrocardiogram.

The number of SAEs reported per participant is indicated in the suffix of the SAE log number. Some participants had two SAEs, as indicated by '002' in bold text.



# Appendix 5 Participant telephone interview topic guide

## Participant telephone interview schedule

### *Preamble script*

Thank you very much for agreeing to participate in this phone interview in order to help us understand what it has been like to be part of the e-coachER study, we really appreciate your time.

Just to recap on the information we sent you, the purpose of this interview is to understand your experience of e-coachER and any impact it may have had so that we can learn for future development. Please say anything you wish, we want to hear all types of feedback and are keen to hear your views on how things might be done differently to improve the study.

The interview will take around 45 minutes and will be audio-taped to ensure that we do not miss anything. All information you provide will be anonymised; if we use any quotes from you we will not give your name but use a false name.

Before we begin do you have any questions about doing the interview?

Are you therefore willing to give consent to do this interview ... thank you.

When we are ready to start I will switch the recorder on, say your name and the date; is that OK?

OK so the recorder is now going on ...

### Take verbal consent

#### **Background**

Can you begin by telling me about why you were prescribed the exercise referral scheme?

How did you hear about e-coachER?

Have you been referred to an exercise centre? Which one? Has a programme been devised for you?

**You should have received a welcome pack in the post – what did you think of the welcome pack?**

How did you find the user guide?

Is there anything you'd recommend we changed about the user guide?

**Did register on e-coachER website? If no:**

It is not a problem that you decided not to visit the website; but we are keen to find out your reasons so we can change things for the better in the future ... so please will you tell me a little bit more about why you did not go to the website? Were there any technical barriers/problems ... was something else putting you off ... **Now conclude interview**

**In general what did you think of the website? (Prompt – what were your first impressions? We will go through it in more detail in a minute)**

So did you register? How was it to do this? ... is there anything that could be changed to help make registering easier?

There was also an e-coachER facilitator to help you with the technology ... did you make use of this? ... in what ways was this helpful? Tell me more about the help you received ... or would have liked to have been given?

**In Step 1** there was a quiz

Do you remember doing this?

What did you think about the quiz?

What were its key messages about the benefits of activity for someone with your condition?

**In Step 2** you were encouraged to find support to get physically active. Can you tell me more about how you used this part of e-coachER?

Did you involve family or friends?

**In Step 2** you were also introduced to the 'Links' pages on the website which gives information about local exercise referral schemes and other local support for becoming physically active. These pages also provided general information about becoming physically active.

Did you use the links?

What did you think about the information provided?

Were the links page useful?

What links were most helpful?

How did you use this support?

**In Step 3** you were asked to use the pedometer to count your steps. This is the little device you wear on your belt.

How did you get on with using this?

In what ways was it useful for you to use the pedometer?

In what ways was the pedometer difficult to use?

Is there anything else you'd like to say about the pedometer, anything we should do differently?

**In Step 4** you were asked to set step count goals.

What did you understand about the purpose/usefulness of setting these goals?

Tell me more about your goal-setting:

Was it easy to set step count goals that were ... specific ... achievable ... realistic ...?

In what ways was the pedometer helpful for achieving your step count goals?

... it was useful (for measuring/seeing progress)?

... it was not helpful because?

In the welcome pack there was a fridge magnet with tear off strips to record your steps.

Did you use these?

Did you put them up on your fridge (or elsewhere)?

How have you used these strips to record your steps?

How have you found these strips useful or not useful?

**In Step 5** you were asked to make some physical activity plans.

Did you use this step to make plans for moderate physical activity?

In what ways was it easy or hard to set weekly goals?

How did you find the advice about setting SMART goals helpful or unhelpful?

In what ways was it easy or hard to keep to a weekly goal?

In what ways was it easy or hard to review your weekly goals?

In what ways was reviewing your step goals helpful or unhelpful?

In this step there was some advice on other opportunities to be physically active, for example, travel, leisure time, household chores.

Did you find this advice helpful or useful?

What did you think about the progress graph? ...

What did you think about the personalised feedback? ... was the praise ... encouragement helpful?

What was it like not to achieve your goals?

To what extent have you used e-coachER to set yourself new step goals each week?

**In Step 6** you were asked about finding ways to help you achieve your physical activity plans. Dealing with the influences in your environment on your physical activity.

Did you use this part of the website? How helpful did you find the advice?

Please tell me a little more about what you did?

Did you make any changes, for example to your daily routine in order to meet your goals?

What did you find most motivating?

Did you make use of the motivational messages/text/e-mails?

**In Step 7** you were asked to identify any barriers or obstacles to carrying on with your physical activity plans. ... how did you get on with this task?

Were you able to identify any causes of stopping your activity programme? (e.g. something to do with your health condition ... holidays ... sickness ... change at work/caring, etc.)

In what way have you found it easy – or not – to challenge negative thoughts about not doing your planned physical activity?

Do you feel you have learned how to plan and avoid lapses in physical activity in the future?

I would like to ask you some more general questions about e-coachER.

How relevant was it for you?

Overall, how did it help you to set and manage your own goals to increase your physical activity?

To what extent did it provide you with new information?

How well were you able to engage with e-coachER?

How easy was e-coachER to navigate? (e.g. layout of 'steps to health'/main menu, goals)

How was the general tone of the website? (Was the language appropriate? Was it supportive? Were the success stories relevant/helpful?)

What did you think about the structure/look of the website? (e.g. font size, colour, length of sessions, ability to unlock sessions after set time period).

When did you use e-coachER – where were you?/what were you doing?

What was the most useful aspect of the e-coachER support package?

Is there anything else that we have not talked about that you would like to discuss about e-coachER?

Did using e-coachER support you in the ERS?

Was e-coachER useful on its own?

Thank participant for their time, etc.

## Interview topic guide for e-coachER study research assistants

Thank you very much for taking part in an interview to talk about your experiences of working on e-coachER. The aim of the interview is hear your views and experiences of what worked well and what could be done differently if a full trial were to be carried out. Additionally, it is hoped that your experiences and views can help to develop a clearer understanding of 'general' issues related to the research process, particularly recruitment of patients to a trial.

Topic	Specific questions and prompts
Background	Can you begin by telling me about your role in the e-coachER trial?
Recruitment/your role in supporting patients through e-coachER	<p>How have you been involved in recruiting participants? Has your role changed during the study?</p> <p>After addressing the earlier recruitment issues, can you tell me about things that worked well in the recruitment process? Anything that did not work so well, even in the later stages of recruitment?</p> <p>What further improvements do you feel could be made to the recruitment process?</p> <p>Is there anything else that you feel is important to consider in relation to recruitment to e-coachER? More generally, to a trial?</p> <p>Could you tell me about the role you played in supporting participants after they had logged on and begun using e-coachER</p>
About the patients	<p>How do you feel patients have felt about (or reacted to) being invited to participate in the study?</p> <p>What do you feel are the main reasons why patients agreed to participate in e-coachER? In a trial?</p> <p>What do you feel have been the main barriers for patients to participating in e-coachER? (Also in relation to invite, reply slips, registration process, logging on?)</p> <p>What do we know about patients opening the information pack and reading the contents? What else could be done to encourage this (for e-coachER, more generally)?</p> <p>After the changes had been made to the protocol, do you feel that anything could/has put participants off (i) opening info pack (ii) returning the reply slips? How can these issues be resolved?</p> <p>What do we know about patients who are signing up for the study but not logging on to e-coachER? What might have put them off?</p> <p>Have you had any feedback from patients about the benefits of e-coachER support/ participating in a trial?</p> <p>Is there anything else you feel is important in relation to what patients have told you about e-coachER/participating in the study? Anything that could have been done differently?</p>
About primary care/ERS	<p>Which primary care/ERS staff were involved in recruitment? How did they recruit to e-coachER?</p> <p>Can you tell me about any feedback you have had from primary care/ERS staff about in the study?</p> <p>Can you tell me about any specific issues faced by different primary care and ERS staff groups when recruiting to e-coachER?</p>
Finishing up	<p>What do you feel is the most beneficial aspect of e-coachER for participants? Least beneficial aspect of the package?</p> <p>What do you feel are the main 'lessons learned' from working on e-coachER, in general and for a larger e-coachER trial?</p> <p>Anything else you feel is important for future recruiting to a trial (i) generally, (ii) for e-coachER?</p>





## Appendix 6 Economic evaluation: overview of unit costs

Type of resource	Unit cost adjusted to 2017/18 prices as appropriate (£)	Source
GP visit at practice (9.22 minutes)	37	PSSRU 2017 <sup>74</sup>
Nurse visit at practice (15.5 minutes)	11	PSSRU 2017 <sup>74</sup>
A&E visit (weighted average accounting for activity)	158	NHS Reference Costs 2015 to 2016 <sup>75</sup>
Social worker visit (30 minutes)	29.50	PSSRU 2017 <sup>74</sup>
Prescriptions	8	PSSRU 2017 <sup>74</sup>
Hospital visit (as outpatient) (weighted average accounting for activity)	137	PSSRU 2017 <sup>74</sup>
GP home visit	135	PSSRU 2010 <sup>88</sup>
Nurse home visit	23	PSSRU 2010 <sup>88</sup>
Physiotherapy appointment (1-hour appointment)	33	PSSRU 2017 <sup>74</sup>
Care worker/advisor visit (30 minutes)	13	PSSRU 2017 <sup>74</sup>
Hospital visit (as day case) (weighted average accounting for activity)	727	PSSRU 2017 <sup>74</sup>
Hospital visit (as inpatient) (weighted average accounting for activity)	1478	NHS Reference Costs 2015 to 2016 <sup>75</sup>
Mental health support (DBT assessment/counsellor)	9	PSSRU 2017 <sup>74</sup>
Dentist	127	PSSRU 2017 <sup>74</sup>
Occupational therapist (1 hour)	35	PSSRU 2017 <sup>74</sup>
Psychiatrist (1 hour)	108	PSSRU 2017 <sup>74</sup>
Psychologist (1 hour)	53	PSSRU 2017 <sup>74</sup>
Podiatrist (1 hour)	33	PSSRU 2017 <sup>74</sup>
Ambulance service	119	PSSRU 2017 <sup>74</sup>
Fitness instructor	7.46	www.payscale.com/research/UK/Job=Fitness_Instructor/Hourly_Rate (accessed 7 May 2018)
Wage rate per hour for participants <sup>a</sup>	Employed (18–21 years, 8.77; 22–29 years, 12.76; 30–39 years, 16.83; 40–49 years, 18.29; 50–59 years, 17.69; ≥ 60 years, 15.69)  Not employed (18–21 years, 4.39; 22–29 years, 6.38; 30–39 years, 8.42; 40–49 years, 9.15; 50–59 years, 8.85; ≥ 60 years, 7.85)	ONS (2017) <sup>76</sup>

DBT, dialectical behaviour therapy; ONS, Office for National Statistics.

<sup>a</sup> Time of employed participants was valued at the full wage rate, and for not employed participants we apply half of that estimate.<sup>89</sup>



## Appendix 7 Economic evaluation: resource use associated with the set-up cost of the intervention

Design was included as these activities may happen in the future following further learning from this trial.

Activity	Resource: discussions with chief investigator and trial manager, review of trial records, diaries and routine administrative records	Total quantity	Cost per participant (unit cost values are omitted to maintain confidentiality) (£)
Design			
Designing of intervention (welcome pack contents)	Time (in hours) spent by:		
	Assistant trial manager	20	8.90
	Professor	20	
	PPI representative (in kind)	20	
Designing of website	Time (in hours) spent by:		
	Technical specialists	960	172.01
	Professor	48	
Publicity campaigns/identification of participants			
Community-based publicity campaigns/identification of participants	Time (in hours) spent by:		
	PPI representatives (in kind)	21	8.21
	Research assistants	84	
	Centre administrators	9	
	Money costs of travel:		
	Car trips	150 miles	0.30
	Advertising:		
	Posters	150 posters	10.00
	Newspaper advert	3 adverts	3.33
Total cost per participant			180.91



## Appendix 8 Economic evaluation: resource use associated with the delivery cost of the intervention

Activity	Resource (from trial records)	Total quantity of resource items	Unit cost (from invoice and trial records) (£)	Cost per patient (£)
Handbooks for participants	Number of handbooks	225	0.04	0.04
Welcome pack boxes	Number of welcome pack unit boxes	225	0.28	0.28
Pedometer	Number of pedometers	225	4.05	4.05
Recording sheets for weekly PA activity (a fridge magnet)	Number of sheets	225	1.01	1.01
Guide for using e-coachER website	Number of website guides	225	0.04	0.04
Postage/packaging of welcome pack	Number of postage packs	225	10.33	10.33
Maintenance/technical support (for participants) of e-coachER website	Time spent (in hours) by:			
	Technical specialist	128	n/a	13.43
	Research assistants	16		
Total cost per participant				29.17
n/a, not applicable.				



## Appendix 9 Economic evaluation: costs of health and social service use

	Cost (£), mean (SD)			
Cost	Whole sample (n = 243)	Control (n = 133)	e-coachER intervention (n = 110)	Which group had higher cost?
Costs at 4 months				
Cost of GP practice visit	85 (89)	84.5 (96)	85 (80)	Intervention
Cost of nurse practice visit	15 (33)	13 (18)	17 (44)	Intervention
Cost of A&E visit	31 (57)	37 (64)	25 (47)	Control
Cost of social worker visit	6 (61)	3 (26)	10 (85)	Intervention
Cost of prescriptions	33 (68)	32 (86)	35 (38)	Intervention
Cost of hospital (outpatients)	133 (184)	136 (189)	130 (178)	Control
Cost of GP home visit	3 (14)	2 (14)	3 (15)	Intervention
Cost of nurse home visit	3 (13)	2 (14)	3 (13)	Intervention
Cost of physiotherapist visit	27 (75)	22 (44)	32 (101)	Intervention
Cost of care worker visit	3 (17)	0.6 (4)	5 (25)	Intervention
Cost of hospital day case	185 (375)	158 (351)	218 (402)	Intervention
Cost of hospital (inpatient)	190 (595)	144 (442)	245 (738)	Intervention
Costs of other health service	8 (57)	4 (34)	12 (77)	Intervention
Total cost at 4 months	721 (952)	639 (842)	819 (1065)	Intervention
Costs at 5–12 months				
Cost of GP practice visit	111 (139)	114 (170)	108 (89)	Control
Cost of nurse practice visit	16 (18)	16 (21)	15 (14)	Control
Cost of A&E visit	24 (65)	27 (74)	20 (53)	Control
Cost of social worker visit	2 (11)	3 (14)	1 (6)	Control
Cost of prescriptions	43 (189)	28 (31)	60 (279)	Intervention
Cost of hospital (outpatients)	132 (221)	136 (250)	128 (180)	Control
Cost of GP home visit	1 (9)	2 (12)	0.5 (4)	Control
Cost of nurse home visit	1 (12)	0.6 (4)	2 (18)	Intervention
Cost of physiotherapist visit	24 (62)	24 (64)	23 (60)	Control
Cost of care worker visit	5 (29)	4 (20)	6 (37)	Intervention
Cost of hospital day case	204 (885)	224 (1119)	180 (472)	Control
Cost of hospital (inpatient)	128 (528)	131 (573)	124 (469)	Control
Costs of other health service	2 (19)	3 (24)	1 (11)	Control
Total cost (5–12 months after the study)	692 (1432)	713 (1761)	668 (891)	Control
Total costs at 12 months	1413 (1971)	1352 (2180)	1487 (1691)	Intervention







EME  
HS&DR  
HTA  
PGfAR  
PHR

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